

N. di protocollo / Protocol No.: **FP-5637/24-fg10**

Data / Date: **2024/09/26**

**Lettera di conferma dell'Organismo Notificato / Notified Body Confirmation
Letter**

Riferimento / Reference: 1002C07224522C_CL

A chi di competenza / To whom it may concern,

Conferma dello stato di una domanda formale, di un accordo scritto e di un'appropriata sorveglianza nell'ambito del Regolamento (UE) 2023/607 che modifica i Regolamenti (UE) 2017/745 e 2017/746 per quanto riguarda le disposizioni transitorie per alcuni dispositivi medici e dispositivi medico-diagnostici in vitro.

Confirmation of the status of a formal application, written agreement, and appropriate surveillance in the framework of Regulation (EU) 2023/607 amending Regulations (EU) 2017/745 and 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices.

La presente lettera conferma che IMQ S.p.A., un Organismo Notificato (nel seguito, "ON") designato ai sensi del Regolamento (UE) 2017/745 (MDR) e identificato con il numero 0051 su NANDO, ha ricevuto una domanda formale in conformità alla sezione 4.3, primo comma dell'Allegato VII del MDR e firmato un accordo scritto in conformità alla sezione 4.3, secondo comma dell'Allegato VII del MDR con il seguente **fabbricante**:

*This letter confirms that IMQ S.p.A., a Notified Body (hereinafter, "NB") designated against Regulation (EU) 2017/745 (MDR) and identified by the number 0051 on NANDO, has received a formal application in accordance with Section 4.3, first subparagraph of Annex VII of MDR and has signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII of MDR with the following **manufacturer**:*

MEDAX SRL Unipersonale

VIA R. PIVA 1/A - 46025 POGGIO RUSCO (MN)

SRN: IT-MF-000024882

IMQ S.p.A. A SOCIO UNICO
SOGGETTA AD ATTIVITÀ DI DIREZIONE
E COORDINAMENTO DI IMQ GROUP S.R.L.

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I dispositivi oggetto della domanda formale e dell'accordo scritto di cui sopra sono identificati nelle Tabelle che seguono; in particolare:

- la Tabella 1 identifica i dispositivi per i quali IMQ S.p.A. ha ricevuto una domanda formale MDR, ha concluso un accordo scritto ed è anche responsabile dell'appropriata sorveglianza dei corrispondenti dispositivi ai sensi della Direttiva 90/385/CEE o della Direttiva 93/42/CEE (nel seguito, "(AI)MDD"),
- la Tabella 2 identifica i dispositivi per i quali IMQ S.p.A. ha ricevuto una domanda formale MDR, ha concluso un accordo scritto ma non ha assunto la responsabilità dell'appropriata sorveglianza dei corrispondenti dispositivi ai sensi della (AI)MDD.

The devices covered by the formal application and the written agreement mentioned above are identified in the Tables below; in particular:

- *Table 1 identifies the devices for which IMQ S.p.A. has received a MDR formal application, has concluded a written agreement and is also responsible for appropriate surveillance of the corresponding devices under the Directive 90/385/EEC or Directive 93/42/EEC (hereinafter, "(AI)MDD"),*
- *Table 2 identifies the devices for which IMQ S.p.A. has received a MDR formal application, has concluded a written agreement but has not taken the responsibility for appropriate surveillance of the corresponding devices under the (AI)MDD.*

Nel caso di dispositivi oggetto di certificati rilasciati ai sensi della (AI)MDD (nel seguito, "certificato (AI)MDD") che sono scaduti dopo il 26 maggio 2021 e prima del 20 marzo 2023, senza essere stati ritirati, questa lettera conferma anche che il fabbricante ha firmato l'accordo scritto ai sensi del MDR entro la data di scadenza del pertinente certificato (AI)MDD oppure ha fornito l'evidenza che un'Autorità Competente di uno Stato membro ha concesso una deroga o un'esenzione dalla procedura di valutazione della conformità applicabile ai sensi, rispettivamente, dell'articolo 59(1) del MDR o dell'articolo 97(1) del MDR, entro il 20 Marzo 2023 per i dispositivi in questione.

In the case of devices covered by certificates issued under (AI)MDD (hereinafter, "(AI)MDD certificate") that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the manufacturer signed the written agreement under MDR by the date of expiry of the relevant (AI)MDD certificate or provided evidence that a Competent Authority of a Member State had granted a derogation or exemption from the applicable conformity assessment procedure in accordance with Article 59(1) of MDR or Article 97(1) of the MDR respectively, by 20 March 2023 for the relevant devices.



Di seguito sono riportati i periodi di transizione che si applicano ai dispositivi oggetto della presente lettera, a condizione che il fabbricante continui a rispettare le altre condizioni specificate nell'articolo 120 (3 quater) del MDR (come modificato dal Regolamento (UE) 2023/607):

- a) 31 dicembre 2027, per tutti i dispositivi della classe III, e per i dispositivi impiantabili della classe IIb ad eccezione delle tecnologie ben consolidate (WET - materiali per sutura, graffette, materiali per otturazioni dentarie, apparecchi ortodontici, corone dentali, viti, cunei, placche e protesi, fili, chiodi, clip e connettori),
- b) 31 dicembre 2028, per i dispositivi della classe IIb diversi da quelli di cui al punto a) che precede, per i dispositivi della classe IIa e per i dispositivi della classe I immessi sul mercato in condizione sterile (Is) o con funzione di misura (Im),
- c) 31 dicembre 2028 per i dispositivi per i quali la procedura di valutazione della conformità a norma della MDD non richiedeva l'intervento di un ON ma per i quali la procedura di valutazione della conformità a norma del MDR richiede l'intervento di un ON, ad esempio, dispositivi della classe I che si qualificano come Strumenti chirurgici riutilizzabili (Ir).

The transition timelines that apply to the devices covered by this letter, subject to the manufacturer's continued compliance to the other conditions specified in Article 120 (3c) of MDR (as amended by Regulation (EU) 2023/607), are shown below:

- a) 31 December 2027, for all class III devices, and for class IIb implantable devices excluding well-established technologies (WET - sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors),
- b) 31 December 2028, for class IIb devices other than those covered by point (a) above, for class IIa devices, and for class I devices placed on the market in sterile condition (Is) or having a measuring function (Im),
- c) 31 December 2028 for devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a NB but for which the conformity assessment procedure pursuant to MDR requires the involvement of a NB, e.g., class I devices that qualify as re-usable surgical instruments (Ir).

Distinti saluti / Best regards

IMQ S.p.A.
Responsabile Divisione Dispositivi Medici
Medical device Division Manager

(B. Venturelli)

A handwritten signature in black ink, appearing to read 'B. Venturelli'.

<p>Tabella 1: Dispositivi oggetto della presente lettera e per i quali IMQ S.p.A. è anche responsabile dell'appropriata sorveglianza dei dispositivi corrispondenti ai sensi della (AI)MDD</p> <p>Table 1: Devices covered by this letter and for which IMQ S.p.A. is also responsible for appropriate surveillance of the corresponding devices under the (AI)MDD</p>			
<p>Dispositivo (Nome o UDI-DI di base) oggetto della Domanda MDR</p> <p>Device (Name or Basic UDI-DI) under MDR application</p>	<p>Classificazione del Dispositivo oggetto della Domanda MDR</p> <p>Classification of the device under MDR application</p> <p>(1)</p>	<p>Se il dispositivo oggetto della Domanda MDR è un dispositivo sostitutivo, identificazione del corrispondente dispositivo (AI)MDD</p> <p>If the device under MDR application is a substitute device, identification of the corresponding (AI)MDD device</p>	<p>Riferimento del/i pertinente/i certificato/i (AI)MDD e identificazione dell'ON</p> <p>Reference to relevant (AI)MDD certificate(s) and the NB identification</p>
<p>Bone marrow aspiration and biopsy needle:</p>			
<p>NXXXXYYY-00</p> <p>where:</p> <ul style="list-style-type: none"> XX = gauge from 08 to 11 YYY = length from 100 mm to 150 mm XX = gauge 13 YYY = length from 70 mm to 150 mm 	Ila	<p>NXXXXYYY-00</p> <p>REFs. are listed in 'Detailed list of MDD Ref. numbers', dated 2024/09/23, here attached.</p>	<p>Certificato /</p> <p>Certificate: G2 063838 0015 Rev.02</p> <p>ON / NB: 0123</p>
<p>ENXXXXYY-10</p> <p>where:</p> <ul style="list-style-type: none"> XX = gauge 11 YYY = length 100 mm XX = gauge 13 YYY = length from 70 mm to 100 mm 	Ila	<p>ENXXXXYY-C0</p> <p>REFs. are listed in 'Detailed list of MDD Ref. numbers', dated 2024/09/23, here attached.</p>	<p>Certificato /</p> <p>Certificate: G2 063838 0015 Rev.02</p> <p>ON / NB: 0123</p>
<p>ENXXXXYY-00</p> <p>where:</p> <ul style="list-style-type: none"> XX = gauge 11 YYY = length 100 mm XX = gauge 13 YYY = length from 70 mm to 100 mm 	Ila	<p>ENXXXXYY-C1</p> <p>REFs. are listed in 'Detailed list of MDD Ref. numbers', dated 2024/09/23, here attached.</p>	<p>Certificato /</p> <p>Certificate: G2 063838 0015 Rev.02</p> <p>ON / NB: 0123</p>

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MBXXYYY-00 where: <ul style="list-style-type: none"> XX = gauge from 08 to 11 YYY = length from 100 mm to 150 mm XX = gauge 13 YYY = length from 70 mm to 150 mm 	Ila	MBXXYYY-00 REFs. are listed in 'Detailed list of MDD Ref. numbers', dated 2024/09/23, here attached.	Certificato / <i>Certificate:</i> G2 063838 0015 Rev.02 ON / NB: 0123
XBXXYYY-00 where: <ul style="list-style-type: none"> XX = gauge from 08 to 11 YYY = length from 100 mm to 150 mm XX = gauge 13 YYY = length from 70 mm to 150 mm 	Ila	n/a REFs. are listed in 'Detailed list of MDD Ref. numbers', dated 2024/09/23, here attached.	Certificato / <i>Certificate:</i> G2 063838 0015 Rev.02 ON / NB: 0123
HMXXYYY-00 where: <ul style="list-style-type: none"> XX = gauge from 08 to 11 YYY = length from 100 mm to 150 mm XX = gauge 13 YYY = length from 70 mm to 150 mm 	Ila	HMXXYYY-00 REFs. are listed in 'Detailed list of MDD Ref. numbers', dated 2024/09/23, here attached.	Certificato / <i>Certificate:</i> G2 063838 0015 Rev.02 ON / NB: 0123

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HFXYYYY-00 where: <ul style="list-style-type: none"> XX = gauge from 08 to 11 YYY = length from 100 mm to 150 mm XX = gauge 13 YYY = length from 70 mm to 150 mm 	Ila	HFXYYYY-02 REFs. are listed in 'Detailed list of MDD Ref. numbers', dated 2024/09/23, here attached.	Certificato / <i>Certificate:</i> G2 063838 0015 Rev.02 ON / NB: 0123
MMXYYYY-00 where: <ul style="list-style-type: none"> XX = gauge from 08 to 11 YYY = length from 100 mm to 150 mm XX = gauge 13 YYY = length from 70 mm to 150 mm 	Ila	MMXYYYY-00 REFs. are listed in 'Detailed list of MDD Ref. numbers', dated 2024/09/23, here attached.	Certificato / <i>Certificate:</i> G2 063838 0015 Rev.02 ON / NB: 0123
MFXYYYY-00 where: <ul style="list-style-type: none"> XX = gauge from 08 to 11 YYY = length from 100 mm to 150 mm XX = gauge 13 YYY = length from 70 mm to 150 mm 	Ila	MFXYYYY-02 REFs. are listed in 'Detailed list of MDD Ref. numbers', dated 2024/09/23, here attached.	Certificato / <i>Certificate:</i> G2 063838 0015 Rev.02 ON / NB: 0123

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XFXXYYY-00 where: XX = gauge from 08 to 11 YYY = length from 100 mm to 150 mm	Ila	XLXXYYY-0P REFs. are listed in 'Detailed list of MDD Ref. numbers', dated 2024/09/23, here attached.	Certificato / <i>Certificate:</i> G2 063838 0015 Rev.02 ON / NB: 0123
XMXXYYY-00 where: <ul style="list-style-type: none"> XX = gauge from 08 to 11 YYY = length from 100 mm to 150 mm XX = gauge 13 YYY = length from 70 mm to 150 mm 	Ila	XLXXYYY-0S REFs. are listed in 'Detailed list of MDD Ref. numbers', dated 2024/09/23, here attached.	Certificato / <i>Certificate:</i> G2 063838 0015 Rev.02 ON / NB: 0123
PSXXYYY-10 where: XX = gauge from 14 to 18 YYY = length from 20 mm to 150 mm	Ila	n/a REFs. are listed in 'Detailed list of MDD Ref. numbers', dated 2024/09/23, here attached.	Certificato / <i>Certificate:</i> G2 063838 0015 Rev.02 ON / NB: 0123
PFXXXYYY-10 where: XX = gauge from 14 to 18 YYY = length from 50 mm to 150 mm	Ila	PFXXXYYY-10 REFs. are listed in 'Detailed list of MDD Ref. numbers', dated 2024/09/23, here attached.	Certificato / <i>Certificate:</i> G2 063838 0015 Rev.02 ON / NB: 0123

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<p>Dispositivo (Nome o UDI-DI di base) oggetto della Domanda MDR</p> <p><i>Device (Name or Basic UDI-DI) under MDR application</i></p>	<p>Classificazione del Dispositivo oggetto della Domanda MDR</p> <p><i>Classification of the device under MDR application</i></p> <p>(1)</p>	<p>Se il dispositivo oggetto della Domanda MDR è un dispositivo sostitutivo, identificazione del corrispondente dispositivo (AI)MDD</p> <p><i>If the device under MDR application is a substitute device, identification of the corresponding (AI)MDD device</i></p>	<p>Riferimento del/i pertinente/i certificato/i (AI)MDD e identificazione dell'ON</p> <p><i>Reference to relevant (AI)MDD certificate(s) and the NB identification</i></p>
<p>MAXYYYY-00</p> <p>where: XX = gauge from 14 to 18 YYY = length from 20 mm to 150 mm</p>	Ila	<p>n/a</p> <p>REFs. are listed in 'Detailed list of MDD Ref. numbers', dated 2024/09/23, here attached.</p>	<p>Certificato / Certificate: G2 063838 0015 Rev.02 ON / NB: 0123</p>
<p>MAXYYYY-10</p> <p>where: XX = gauge from 14 to 18 YYY = length from 20 mm to 150 mm</p>	Ila	<p>MAXYYYY-10 PSXXXXY-E0</p> <p>REFs. are listed in 'Detailed list of MDD Ref. numbers', dated 2024/09/23, here attached.</p>	<p>Certificato / Certificate: G2 063838 0015 Rev.02 ON / NB: 0123</p>
<p>XSXXXXY-00</p> <p>where: XX = gauge from 15 to 18 YYY = length from 30 mm to 50 mm</p>	Ila	<p>XSXXXXY-01</p> <p>REFs. are listed in 'Detailed list of MDD Ref. numbers', dated 2024/09/23, here attached.</p>	<p>Certificato / Certificate: G2 063838 0015 Rev.02 ON / NB: 0123</p>
<p>XSXXXXY-10</p> <p>where: XX = gauge from 15 to 18 YYY = length from 30 mm to 50 mm</p>	Ila	<p>XSXXXXY-11</p> <p>REFs. are listed in 'Detailed list of MDD Ref. numbers', dated 2024/09/23, here attached.</p>	<p>Certificato / Certificate: G2 063838 0015 Rev.02 ON / NB: 0123</p>

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HNXXYYY-00 where: XX = gauge from 14 to 18 YYY = length from 30 mm to 110 mm	Ila	n/a REFs. are listed in 'Detailed list of MDD Ref. numbers', dated 2024/09/23, here attached.	Certificato / Certificate: G2 063838 0015 Rev.02 ON / NB: 0123
HDXXYYY-00 where: XX = gauge from 14 to 18 YYY = length from 50 mm to 150 mm	Ila	HDXXYYY-00 REFs. are listed in 'Detailed list of MDD Ref. numbers', dated 2024/09/23, here attached.	Certificato / Certificate: G2 063838 0015 Rev.02 ON / NB: 0123
XIXXXYYY-00 where: XX = gauge from 15 to 18 YYY = length from 30 mm to 50 mm	Ila	XIXXXYYY-01 REFs. are listed in 'Detailed list of MDD Ref. numbers', dated 2024/09/23, here attached.	Certificato / Certificate: G2 063838 0015 Rev.02 ON / NB: 0123

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<p>XJXXYYY-00</p> <p>where:</p> <ul style="list-style-type: none"> XX = gauge 08 YYY = length 100 mm XX = gauge 11 YYY = length from 100 mm to 150 mm XX = gauge 13 YYY = length from 50 mm to 90 mm 	Ila	<p>n/a</p> <p>REFs. are listed in 'Detailed list of MDD Ref. numbers', dated 2024/09/23, here attached.</p>	<p>Certificato / Certificate: G2 063838 0015 Rev.02</p> <p>ON / NB: 0123</p>
<p>Soft tissue biopsy needles:</p>			
<p>HP-XXYYY-00</p> <p>where:</p> <p>XX = gauge from 15 to 18 YYY = length 88 mm</p>	Ila	<p>HKXXYYY-M0</p> <p>REFs. are listed in 'Detailed list of MDD Ref. numbers', dated 2024/09/23, here attached.</p>	<p>Certificato / Certificate: G2 063838 0015 Rev.02</p> <p>ON / NB: 0123</p>
<p>SMXXYYY-00</p> <p>where:</p> <p>XX = gauge from 17 to 21 YYY = length from 100 mm to 160 mm</p>	Ila	<p>HXXYYY-M0</p> <p>REFs. are listed in 'Detailed list of MDD Ref. numbers', dated 2024/09/23, here attached.</p>	<p>Certificato / Certificate: G2 063838 0015 Rev.02</p> <p>ON / NB: 0123</p>

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CHXXYYY-00 where: <ul style="list-style-type: none"> XX = gauge from 18 to 22 YYY = length from 80 to 300 mm XX = gauge from 23 to 25 YYY = length from 40 mm to 200 mm 	Ila	n/a REFs. are listed in 'Detailed list of MDD Ref. numbers', dated 2024/09/23, here attached.	Certificato / <i>Certificate:</i> G2 063838 0015 Rev.02 ON / NB: 0123
CHXXYYY-01 where: <ul style="list-style-type: none"> XX = gauge from 18 to 22 YYY = length from 80 to 300 mm XX = gauge from 23 to 25 YYY = length from 40 mm to 200 mm 	Ila	n/a REFs. are listed in 'Detailed list of MDD Ref. numbers', dated 2024/09/23, here attached.	Certificato / <i>Certificate:</i> G2 063838 0015 Rev.02 ON / NB: 0123
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Dispositivo (Nome o UDI-DI di base) oggetto della Domanda MDR <i>Device (Name or Basic UDI-DI) under MDR application</i>	Classificazione del Dispositivo oggetto della Domanda MDR <i>Classification of the device under MDR application</i> (1)	Se il dispositivo oggetto della Domanda MDR è un dispositivo sostitutivo, identificazione del corrispondente dispositivo (AI)MDD <i>If the device under MDR application is a substitute device, identification of the corresponding (AI)MDD device</i>	Riferimento del/i pertinente/i certificato/i (AI)MDD e identificazione dell'ON <i>Reference to relevant (AI)MDD certificate(s) and the NB identification</i>
QKXXYYY-01 where: <ul style="list-style-type: none"> XX = gauge from 18 to 22 YYY = length from 80 to 300 mm XX = gauge from 23 to 25 YYY = length from 40 mm to 200 mm 	Ila	n/a REFs. are listed in 'Detailed list of MDD Ref. numbers', dated 2024/09/23, here attached.	Certificato / <i>Certificate:</i> G2 063838 0015 Rev.02 ON / NB: 0123
FRXXYYY-00 where: XX = gauge from 18 to 22 YYY = length from 80 mm to 300 mm	Ila	n/a REFs. are listed in 'Detailed list of MDD Ref. numbers', dated 2024/09/23, here attached.	Certificato / <i>Certificate:</i> G2 063838 0015 Rev.02 ON / NB: 0123
FRXXYYY-01 where: XX = gauge from 18 to 22 YYY = length from 80 mm to 300 mm	Ila	n/a REFs. are listed in 'Detailed list of MDD Ref. numbers', dated 2024/09/23, here attached.	Certificato / <i>Certificate:</i> G2 063838 0015 Rev.02 ON / NB: 0123
WEXXXYYY-00 where: XX = gauge from 18 to 22 YYY = length from 80 mm to 300 mm	Ila	n/a REFs. are listed in 'Detailed list of MDD Ref. numbers', dated 2024/09/23, here attached.	Certificato / <i>Certificate:</i> G2 063838 0015 Rev.02 ON / NB: 0123

<p>Tabella 1: Dispositivi oggetto della presente lettera e per i quali IMQ S.p.A. è anche responsabile dell'appropriata sorveglianza dei dispositivi corrispondenti ai sensi della (AI)MDD</p> <p><i>Table 1: Devices covered by this letter and for which IMQ S.p.A. is also responsible for appropriate surveillance of the corresponding devices under the (AI)MDD</i></p>			
<p>Dispositivo (Nome o UDI-DI di base) oggetto della Domanda MDR</p> <p><i>Device (Name or Basic UDI-DI) under MDR application</i></p>	<p>Classificazione del Dispositivo oggetto della Domanda MDR</p> <p><i>Classification of the device under MDR application</i></p> <p>(1)</p>	<p>Se il dispositivo oggetto della Domanda MDR è un dispositivo sostitutivo, identificazione del corrispondente dispositivo (AI)MDD</p> <p><i>If the device under MDR application is a substitute device, identification of the corresponding (AI)MDD device</i></p>	<p>Riferimento del/i pertinente/i certificato/i (AI)MDD e identificazione dell'ON</p> <p><i>Reference to relevant (AI)MDD certificate(s) and the NB identification</i></p>
<p>WEXYYYY-01</p> <p>where: XX = gauge from 18 to 22 YYY = length from 80 mm to 300 mm</p>	IIa	<p>n/a</p> <p>REFs. are listed in 'Detailed list of MDD Ref. numbers', dated 2024/09/23, here attached.</p>	<p>Certificato / Certificate: G2 063838 0015 Rev.02 ON / NB: 0123</p>
<p>AMXYYYY-00</p> <p>where: XX = gauge from 18 to 23 YYY = length from 100 mm to 200 mm</p>	IIa	<p>n/a</p> <p>REFs. are listed in 'Detailed list of MDD Ref. numbers', dated 2024/09/23, here attached.</p>	<p>Certificato / Certificate: G2 063838 0015 Rev.02 ON / NB: 0123</p>
<p>VLXYYYY-00</p> <p>where: XX = gauge from 19 to 20 YYY = length from 160 mm to 200 mm</p>	IIa	<p>VLXYYYY-00</p> <p>REFs. are listed in 'Detailed list of MDD Ref. numbers', dated 2024/09/23, here attached.</p>	<p>Certificato / Certificate: G2 063838 0015 Rev.02 ON / NB: 0123</p>
<p>VKXYYYY-00</p> <p>where: XX = gauge from 20 to 21 YYY = length from 160 mm to 200 mm</p>	IIa	<p>n/a</p> <p>REFs. are listed in 'Detailed list of MDD Ref. numbers', dated 2024/09/23, here attached.</p>	<p>Certificato / Certificate: G2 063838 0015 Rev.02 ON / NB: 0123</p>

Tabella 1: Dispositivi oggetto della presente lettera e per i quali IMQ S.p.A. è anche responsabile dell'appropriata sorveglianza dei dispositivi corrispondenti ai sensi della (AI)MDD

Table 1: Devices covered by this letter and for which IMQ S.p.A. is also responsible for appropriate surveillance of the corresponding devices under the (AI)MDD

Dispositivo (Nome o UDI-DI di base) oggetto della Domanda MDR <i>Device (Name or Basic UDI-DI) under MDR application</i>	Classificazione del Dispositivo oggetto della Domanda MDR <i>Classification of the device under MDR application</i> (1)	Se il dispositivo oggetto della Domanda MDR è un dispositivo sostitutivo, identificazione del corrispondente dispositivo (AI)MDD <i>If the device under MDR application is a substitute device, identification of the corresponding (AI)MDD device</i>	Riferimento del/i pertinente/i certificato/i (AI)MDD e identificazione dell'ON <i>Reference to relevant (AI)MDD certificate(s) and the NB identification</i>
LTXXYYY-00 where: XX = gauge from 14 to 20 YYY = length from 80 mm to 300 mm	Ila	LTXXYYY-00 REFs. are listed in 'Detailed list of MDD Ref. numbers', dated 2024/09/23, here attached.	Certificato / Certificate: G2 063838 0015 Rev.02 ON / NB: 0123
LTXXYYY-01 where: XX = gauge from 14 to 20 YYY = length from 80 mm to 300 mm	Ila	LTXXYYY-01 REFs. are listed in 'Detailed list of MDD Ref. numbers', dated 2024/09/23, here attached.	Certificato / Certificate: G2 063838 0015 Rev.02 ON / NB: 0123
VTXXYYY-00 where: XX = gauge from 14 to 20 YYY = length from 80 mm to 300 mm	Ila	VTXXYYY-00 REFs. are listed in 'Detailed list of MDD Ref. numbers', dated 2024/09/23, here attached.	Certificato / Certificate: G2 063838 0015 Rev.02 ON / NB: 0123
VTXXYYY-01 where: XX = gauge from 14 to 20 YYY = length from 80 mm to 300 mm	Ila	VTXXYYY-01 REFs. are listed in 'Detailed list of MDD Ref. numbers', dated 2024/09/23, here attached.	Certificato / Certificate: G2 063838 0015 Rev.02 ON / NB: 0123

Tabella 1: Dispositivi oggetto della presente lettera e per i quali IMQ S.p.A. è anche responsabile dell'appropriata sorveglianza dei dispositivi corrispondenti ai sensi della (AI)MDD

Table 1: Devices covered by this letter and for which IMQ S.p.A. is also responsible for appropriate surveillance of the corresponding devices under the (AI)MDD

Dispositivo (Nome o UDI-DI di base) oggetto della Domanda MDR <i>Device (Name or Basic UDI-DI) under MDR application</i>	Classificazione del Dispositivo oggetto della Domanda MDR <i>Classification of the device under MDR application</i> (1)	Se il dispositivo oggetto della Domanda MDR è un dispositivo sostitutivo, identificazione del corrispondente dispositivo (AI)MDD <i>If the device under MDR application is a substitute device, identification of the corresponding (AI)MDD device</i>	Riferimento del/i pertinente/i certificato/i (AI)MDD e identificazione dell'ON <i>Reference to relevant (AI)MDD certificate(s) and the NB identification</i>
VTXXYYY-C0 where: XX = gauge from 14 to 20 YYY = length from 80 mm to 300 mm	Ila	VTXXYYY-C0 REFs. are listed in 'Detailed list of MDD Ref. numbers', dated 2024/09/23, here attached.	Certificato / Certificate: G2 063838 0015 Rev.02 ON / NB: 0123
VTXXYYY-C1 where: XX = gauge from 14 to 20 YYY = length from 80 mm to 300 mm	Ila	VTXXYYY-C1 REFs. are listed in 'Detailed list of MDD Ref. numbers', dated 2024/09/23, here attached.	Certificato / Certificate: G2 063838 0015 Rev.02 ON / NB: 0123
VTXXYYY-K0 where: XX = gauge from 14 to 20 YYY = length from 80 mm to 300 mm	Ila	VTXXYYY-K0 REFs. are listed in 'Detailed list of MDD Ref. numbers', dated 2024/09/23, here attached.	Certificato / Certificate: G2 063838 0015 Rev.02 ON / NB: 0123
VTXXYYY-K1 where: XX = gauge from 14 to 20 YYY = length from 80 mm to 300 mm	Ila	VTXXYYY-K1 REFs. are listed in 'Detailed list of MDD Ref. numbers', dated 2024/09/23, here attached.	Certificato / Certificate: G2 063838 0015 Rev.02 ON / NB: 0123

Tabella 1: Dispositivi oggetto della presente lettera e per i quali IMQ S.p.A. è anche responsabile dell'appropriata sorveglianza dei dispositivi corrispondenti ai sensi della (AI)MDD

Table 1: Devices covered by this letter and for which IMQ S.p.A. is also responsible for appropriate surveillance of the corresponding devices under the (AI)MDD

Dispositivo (Nome o UDI-DI di base) oggetto della Domanda MDR <i>Device (Name or Basic UDI-DI) under MDR application</i>	Classificazione del Dispositivo oggetto della Domanda MDR <i>Classification of the device under MDR application</i> (1)	Se il dispositivo oggetto della Domanda MDR è un dispositivo sostitutivo, identificazione del corrispondente dispositivo (AI)MDD <i>If the device under MDR application is a substitute device, identification of the corresponding (AI)MDD device</i>	Riferimento del/i pertinente/i certificato/i (AI)MDD e identificazione dell'ON <i>Reference to relevant (AI)MDD certificate(s) and the NB identification</i>
BFXXYYY-00 where: XX = gauge from 12 to 20 YYY = length from 80 mm to 300 mm	Ila	BFXXYYY-00 REFs. are listed in 'Detailed list of MDD Ref. numbers', dated 2024/09/23, here attached.	Certificato / Certificate: G2 063838 0015 Rev.02 ON / NB: 0123
BFXXYYY-01 where: XX = gauge from 12 to 20 YYY = length from 80 mm to 300 mm	Ila	BFXXYYY-01 REFs. are listed in 'Detailed list of MDD Ref. numbers', dated 2024/09/23, here attached.	Certificato / Certificate: G2 063838 0015 Rev.02 ON / NB: 0123
BFXXYYY-02 where: XX = gauge from 12 to 20 YYY = length from 80 mm to 300 mm	Ila	BFXXYYY-02 REFs. are listed in 'Detailed list of MDD Ref. numbers', dated 2024/09/23, here attached.	Certificato / Certificate: G2 063838 0015 Rev.02 ON / NB: 0123
BFXXYYY-C0 where: XX = gauge from 12 to 20 YYY = length from 80 mm to 300 mm	Ila	BFXXYYY-C0 REFs. are listed in 'Detailed list of MDD Ref. numbers', dated 2024/09/23, here attached.	Certificato / Certificate: G2 063838 0015 Rev.02 ON / NB: 0123

Tabella 1: Dispositivi oggetto della presente lettera e per i quali IMQ S.p.A. è anche responsabile dell'appropriata sorveglianza dei dispositivi corrispondenti ai sensi della (AI)MDD

Table 1: Devices covered by this letter and for which IMQ S.p.A. is also responsible for appropriate surveillance of the corresponding devices under the (AI)MDD

Dispositivo (Nome o UDI-DI di base) oggetto della Domanda MDR <i>Device (Name or Basic UDI-DI) under MDR application</i>	Classificazione del Dispositivo oggetto della Domanda MDR <i>Classification of the device under MDR application</i> (1)	Se il dispositivo oggetto della Domanda MDR è un dispositivo sostitutivo, identificazione del corrispondente dispositivo (AI)MDD <i>If the device under MDR application is a substitute device, identification of the corresponding (AI)MDD device</i>	Riferimento del/i pertinente/i certificato/i (AI)MDD e identificazione dell'ON <i>Reference to relevant (AI)MDD certificate(s) and the NB identification</i>
BFXXYYY-C1 where: XX = gauge from 12 to 20 YYY = length from 80 mm to 300 mm	Ila	BFXXYYY-C1 REFs. are listed in 'Detailed list of MDD Ref. numbers', dated 2024/09/23, here attached.	Certificato / Certificate: G2 063838 0015 Rev.02 ON / NB: 0123
BFXXYYY-C2 where: XX = gauge from 12 to 20 YYY = length from 80 mm to 300 mm	Ila	BFXXYYY-C2 REFs. are listed in 'Detailed list of MDD Ref. numbers', dated 2024/09/23, here attached.	Certificato / Certificate: G2 063838 0015 Rev.02 ON / NB: 0123
BFXXYYY-K0 where: XX = gauge from 12 to 20 YYY = length from 80 mm to 300 mm	Ila	BFXXYYY-K0 REFs. are listed in 'Detailed list of MDD Ref. numbers', dated 2024/09/23, here attached.	Certificato / Certificate: G2 063838 0015 Rev.02 ON / NB: 0123
BFXXYYY-K1 where: XX = gauge from 12 to 20 YYY = length from 80 mm to 300 mm	Ila	BFXXYYY-K1 REFs. are listed in 'Detailed list of MDD Ref. numbers', dated 2024/09/23, here attached.	Certificato / Certificate: G2 063838 0015 Rev.02 ON / NB: 0123

<p>Tabella 1: Dispositivi oggetto della presente lettera e per i quali IMQ S.p.A. è anche responsabile dell'appropriata sorveglianza dei dispositivi corrispondenti ai sensi della (AI)MDD</p> <p><i>Table 1: Devices covered by this letter and for which IMQ S.p.A. is also responsible for appropriate surveillance of the corresponding devices under the (AI)MDD</i></p>			
<p>Dispositivo (Nome o UDI-DI di base) oggetto della Domanda MDR</p> <p><i>Device (Name or Basic UDI-DI) under MDR application</i></p>	<p>Classificazione del Dispositivo oggetto della Domanda MDR</p> <p><i>Classification of the device under MDR application</i></p> <p>(1)</p>	<p>Se il dispositivo oggetto della Domanda MDR è un dispositivo sostitutivo, identificazione del corrispondente dispositivo (AI)MDD</p> <p><i>If the device under MDR application is a substitute device, identification of the corresponding (AI)MDD device</i></p>	<p>Riferimento del/i pertinente/i certificato/i (AI)MDD e identificazione dell'ON</p> <p><i>Reference to relevant (AI)MDD certificate(s) and the NB identification</i></p>
<p>BFXXYYY-K2</p> <p>where: XX = gauge from 12 to 20 YYY = length from 80 mm to 300 mm</p>	Ila	<p>BFXXYYY-K2</p> <p>REFs. are listed in 'Detailed list of MDD Ref. numbers', dated 2024/09/23, here attached.</p>	<p>Certificato / Certificate: G2 063838 0015 Rev.02 ON / NB: 0123</p>
<p>MLXXYYY-00</p> <p>where: XX = gauge from 12 to 20 YYY = length from 60 mm to 300 mm</p>	Ila	<p>MLXXYYY-00</p> <p>REFs. are listed in 'Detailed list of MDD Ref. numbers', dated 2024/09/23, here attached.</p>	<p>Certificato / Certificate: G2 063838 0015 Rev.02 ON / NB: 0123</p>
<p>MLXXYYY-C0</p> <p>where: XX = gauge from 12 to 20 YYY = length from 60 mm to 300 mm</p>	Ila	<p>MLXXYYY-C0</p> <p>REFs. are listed in 'Detailed list of MDD Ref. numbers', dated 2024/09/23, here attached.</p>	<p>Certificato / Certificate: G2 063838 0015 Rev.02 ON / NB: 0123</p>
<p>MLXXYYY-K0</p> <p>where: XX = gauge from 12 to 20 YYY = length from 60 mm to 300 mm</p>	Ila	<p>MLXXYYY-K0</p> <p>REFs. are listed in 'Detailed list of MDD Ref. numbers', dated 2024/09/23, here attached.</p>	<p>Certificato / Certificate: G2 063838 0015 Rev.02 ON / NB: 0123</p>

<p>Tabella 1: Dispositivi oggetto della presente lettera e per i quali IMQ S.p.A. è anche responsabile dell'appropriata sorveglianza dei dispositivi corrispondenti ai sensi della (AI)MDD</p> <p><i>Table 1: Devices covered by this letter and for which IMQ S.p.A. is also responsible for appropriate surveillance of the corresponding devices under the (AI)MDD</i></p>			
<p>Dispositivo (Nome o UDI-DI di base) oggetto della Domanda MDR</p> <p><i>Device (Name or Basic UDI-DI) under MDR application</i></p>	<p>Classificazione del Dispositivo oggetto della Domanda MDR</p> <p><i>Classification of the device under MDR application</i></p> <p>(1)</p>	<p>Se il dispositivo oggetto della Domanda MDR è un dispositivo sostitutivo, identificazione del corrispondente dispositivo (AI)MDD</p> <p><i>If the device under MDR application is a substitute device, identification of the corresponding (AI)MDD device</i></p>	<p>Riferimento del/i pertinente/i certificato/i (AI)MDD e identificazione dell'ON</p> <p><i>Reference to relevant (AI)MDD certificate(s) and the NB identification</i></p>
<p>MSXXYYY-00</p> <p>where: XX = gauge from 12 to 20 YYY = length from 60 mm to 300 mm</p>	Ila	<p>MSXXYYY-02</p> <p>REFs. are listed in 'Detailed list of MDD Ref. numbers', dated 2024/09/23, here attached.</p>	<p>Certificato / Certificate: G2 063838 0015 Rev.02 ON / NB: 0123</p>
<p>MSXXYYY-C0</p> <p>where: XX = gauge from 12 to 20 YYY = length from 60 mm to 300 mm</p>	Ila	<p>MSXXYYY-C2</p> <p>REFs. are listed in 'Detailed list of MDD Ref. numbers', dated 2024/09/23, here attached.</p>	<p>Certificato / Certificate: G2 063838 0015 Rev.02 ON / NB: 0123</p>
<p>MSXXYYY-K0</p> <p>where: XX = gauge from 12 to 20 YYY = length from 60 mm to 300 mm</p>	Ila	<p>MSXXYYY-K2</p> <p>REFs. are listed in 'Detailed list of MDD Ref. numbers', dated 2024/09/23, here attached.</p>	<p>Certificato / Certificate: G2 063838 0015 Rev.02 ON / NB: 0123</p>
<p>MCXXYYY-00</p> <p>where: XX = gauge from 12 to 20 YYY = length from 80 mm to 300 mm</p>	Ila	<p>n/a</p> <p>REFs. are listed in 'Detailed list of MDD Ref. numbers', dated 2024/09/23, here attached.</p>	<p>Certificato / Certificate: G2 063838 0015 Rev.02 ON / NB: 0123</p>

Tabella 1: Dispositivi oggetto della presente lettera e per i quali IMQ S.p.A. è anche responsabile dell'appropriata sorveglianza dei dispositivi corrispondenti ai sensi della (AI)MDD Table 1: Devices covered by this letter and for which IMQ S.p.A. is also responsible for appropriate surveillance of the corresponding devices under the (AI)MDD			
Dispositivo (Nome o UDI-DI di base) oggetto della Domanda MDR Device (Name or Basic UDI-DI) under MDR application	Classificazione del Dispositivo oggetto della Domanda MDR Classification of the device under MDR application (1)	Se il dispositivo oggetto della Domanda MDR è un dispositivo sostitutivo, identificazione del corrispondente dispositivo (AI)MDD If the device under MDR application is a substitute device, identification of the corresponding (AI)MDD device	Riferimento del/i pertinente/i certificato/i (AI)MDD e identificazione dell'ON Reference to relevant (AI)MDD certificate(s) and the NB identification
MCXXYYY-01 where: XX = gauge from 12 to 20 YYY = length from 80 mm to 300 mm	Ila	n/a REFs. are listed in 'Detailed list of MDD Ref. numbers', dated 2024/09/23, here attached.	Certificato / Certificate: G2 063838 0015 Rev.02 ON / NB: 0123
MCXXYYY-C0 where: XX = gauge from 12 to 20 YYY = length from 80 mm to 300 mm	Ila	n/a REFs. are listed in 'Detailed list of MDD Ref. numbers', dated 2024/09/23, here attached.	Certificato / Certificate: G2 063838 0015 Rev.02 ON / NB: 0123
MCXXYYY-C1 where: XX = gauge from 12 to 20 YYY = length from 80 mm to 300 mm	Ila	n/a REFs. are listed in 'Detailed list of MDD Ref. numbers', dated 2024/09/23, here attached.	Certificato / Certificate: G2 063838 0015 Rev.02 ON / NB: 0123
MCXXYYY-K0 where: XX = gauge from 12 to 20 YYY = length from 80 mm to 300 mm	Ila	n/a REFs. are listed in 'Detailed list of MDD Ref. numbers', dated 2024/09/23, here attached.	Certificato / Certificate: G2 063838 0015 Rev.02 ON / NB: 0123

<p>Tabella 1: Dispositivi oggetto della presente lettera e per i quali IMQ S.p.A. è anche responsabile dell'appropriata sorveglianza dei dispositivi corrispondenti ai sensi della (AI)MDD</p> <p><i>Table 1: Devices covered by this letter and for which IMQ S.p.A. is also responsible for appropriate surveillance of the corresponding devices under the (AI)MDD</i></p>			
<p>Dispositivo (Nome o UDI-DI di base) oggetto della Domanda MDR</p> <p><i>Device (Name or Basic UDI-DI) under MDR application</i></p>	<p>Classificazione del Dispositivo oggetto della Domanda MDR</p> <p><i>Classification of the device under MDR application</i></p> <p>(1)</p>	<p>Se il dispositivo oggetto della Domanda MDR è un dispositivo sostitutivo, identificazione del corrispondente dispositivo (AI)MDD</p> <p><i>If the device under MDR application is a substitute device, identification of the corresponding (AI)MDD device</i></p>	<p>Riferimento del/i pertinente/i certificato/i (AI)MDD e identificazione dell'ON</p> <p><i>Reference to relevant (AI)MDD certificate(s) and the NB identification</i></p>
<p>MCXXYYY-K1</p> <p>where: XX = gauge from 12 to 20 YYY = length from 80 mm to 300 mm</p>	<p>Ia</p>	<p>n/a</p> <p>REFs. are listed in 'Detailed list of MDD Ref. numbers', dated 2024/09/23, here attached.</p>	<p>Certificato / Certificate: G2 063838 0015 Rev.02 ON / NB: 0123</p>
<p>MNXXYYY-00</p> <p>where: XX = gauge from 12 to 20 YYY = length from 80 mm to 300 mm</p>	<p>Ia</p>	<p>MCXXYYY-0S</p> <p>REFs. are listed in 'Detailed list of MDD Ref. numbers', dated 2024/09/23, here attached.</p>	<p>Certificato / Certificate: G2 063838 0015 Rev.02 ON / NB: 0123</p>
<p>MNXXYYY-01</p> <p>where: XX = gauge from 12 to 20 YYY = length from 80 mm to 300 mm</p>	<p>Ia</p>	<p>MCXXYYY-0T</p> <p>REFs. are listed in 'Detailed list of MDD Ref. numbers', dated 2024/09/23, here attached.</p>	<p>Certificato / Certificate: G2 063838 0015 Rev.02 ON / NB: 0123</p>
<p>MNXXYYY-C0</p> <p>where: XX = gauge from 12 to 20 YYY = length from 80 mm to 300 mm</p>	<p>Ia</p>	<p>MCXXYYY-CS</p> <p>REFs. are listed in 'Detailed list of MDD Ref. numbers', dated 2024/09/23, here attached.</p>	<p>Certificato / Certificate: G2 063838 0015 Rev.02 ON / NB: 0123</p>

<p>Tabella 1: Dispositivi oggetto della presente lettera e per i quali IMQ S.p.A. è anche responsabile dell'appropriata sorveglianza dei dispositivi corrispondenti ai sensi della (AI)MDD</p> <p><i>Table 1: Devices covered by this letter and for which IMQ S.p.A. is also responsible for appropriate surveillance of the corresponding devices under the (AI)MDD</i></p>			
<p>Dispositivo (Nome o UDI-DI di base) oggetto della Domanda MDR</p> <p><i>Device (Name or Basic UDI-DI) under MDR application</i></p>	<p>Classificazione del Dispositivo oggetto della Domanda MDR</p> <p><i>Classification of the device under MDR application</i></p> <p>(1)</p>	<p>Se il dispositivo oggetto della Domanda MDR è un dispositivo sostitutivo, identificazione del corrispondente dispositivo (AI)MDD</p> <p><i>If the device under MDR application is a substitute device, identification of the corresponding (AI)MDD device</i></p>	<p>Riferimento del/i pertinente/i certificato/i (AI)MDD e identificazione dell'ON</p> <p><i>Reference to relevant (AI)MDD certificate(s) and the NB identification</i></p>
<p>MNXXYYY-C1</p> <p>where:</p> <p>XX = gauge from 12 to 20</p> <p>YYY = length from 80 mm to 300 mm</p>	Ila	<p>MCXXYYY-CT</p> <p>REFs. are listed in 'Detailed list of MDD Ref. numbers', dated 2024/09/23, here attached.</p>	<p>Certificato /</p> <p><i>Certificate:</i> G2 063838 0015 Rev.02</p> <p>ON / NB: 0123</p>
<p>MUXXXYYY-00</p> <p>where:</p> <ul style="list-style-type: none"> XX = gauge from 12 to 16 and 20 YYY = length from 60 to 200 mm XX = gauge 18 YYY = length from 60 mm to 250 mm 	Ila	<p>MUXXXYYY-00</p> <p>REFs. are listed in 'Detailed list of MDD Ref. numbers', dated 2024/09/23, here attached.</p>	<p>Certificato /</p> <p><i>Certificate:</i> G2 063838 0015 Rev.02</p> <p>ON / NB: 0123</p>
<p>MUXXXYYY-C0</p> <p>where:</p> <ul style="list-style-type: none"> XX = gauge from 12 to 16 and 20 YYY = length from 60 to 200 mm XX = gauge 18 YYY = length from 60 mm to 250 mm 	Ila	<p>MUXXXYYY-C0</p> <p>REFs. are listed in 'Detailed list of MDD Ref. numbers', dated 2024/09/23, here attached.</p>	<p>Certificato /</p> <p><i>Certificate:</i> G2 063838 0015 Rev.02</p> <p>ON / NB: 0123</p>

Tabella 1: Dispositivi oggetto della presente lettera e per i quali IMQ S.p.A. è anche responsabile dell'appropriata sorveglianza dei dispositivi corrispondenti ai sensi della (AI)MDD

Table 1: Devices covered by this letter and for which IMQ S.p.A. is also responsible for appropriate surveillance of the corresponding devices under the (AI)MDD

Dispositivo (Nome o UDI-DI di base) oggetto della Domanda MDR <i>Device (Name or Basic UDI-DI) under MDR application</i>	Classificazione del Dispositivo oggetto della Domanda MDR <i>Classification of the device under MDR application</i> (1)	Se il dispositivo oggetto della Domanda MDR è un dispositivo sostitutivo, identificazione del corrispondente dispositivo (AI)MDD <i>If the device under MDR application is a substitute device, identification of the corresponding (AI)MDD device</i>	Riferimento del/i pertinente/i certificato/i (AI)MDD e identificazione dell'ON <i>Reference to relevant (AI)MDD certificate(s) and the NB identification</i>
MUXYYYY-K0 where: <ul style="list-style-type: none"> XX = gauge from 12 to 16 and 20 YYY = length from 60 to 200 mm XX = gauge 18 YYY = length from 60 mm to 250 mm 	Ila	MUXYYYY-K0 REFs. are listed in 'Detailed list of MDD Ref. numbers', dated 2024/09/23, here attached.	Certificato / <i>Certificate:</i> G2 063838 0015 Rev.02 ON / NB: 0123
MOXYYYY-00 where: XX = gauge from 12 to 20 YYY = length from 80 mm to 300 mm	Ila	n/a REFs. are listed in 'Detailed list of MDD Ref. numbers', dated 2024/09/23, here attached.	Certificato / <i>Certificate:</i> G2 063838 0015 Rev.02 ON / NB: 0123
MOXYYYY-01 where: XX = gauge from 12 to 20 YYY = length from 80 mm to 300 mm	Ila	n/a REFs. are listed in 'Detailed list of MDD Ref. numbers', dated 2024/09/23, here attached.	Certificato / <i>Certificate:</i> G2 063838 0015 Rev.02 ON / NB: 0123
MOXYYYY-C0 where: XX = gauge from 12 to 20 YYY = length from 80 mm to 300 mm	Ila	n/a REFs. are listed in 'Detailed list of MDD Ref. numbers', dated 2024/09/23, here attached.	Certificato / <i>Certificate:</i> G2 063838 0015 Rev.02 ON / NB: 0123

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Table 1: Devices covered by this letter and for which IMQ S.p.A. is also responsible for appropriate surveillance of the corresponding devices under the (AI)MDD

Dispositivo (Nome o UDI-DI di base) oggetto della Domanda MDR <i>Device (Name or Basic UDI-DI) under MDR application</i>	Classificazione del Dispositivo oggetto della Domanda MDR <i>Classification of the device under MDR application</i> (1)	Se il dispositivo oggetto della Domanda MDR è un dispositivo sostitutivo, identificazione del corrispondente dispositivo (AI)MDD <i>If the device under MDR application is a substitute device, identification of the corresponding (AI)MDD device</i>	Riferimento del/i pertinente/i certificato/i (AI)MDD e identificazione dell'ON <i>Reference to relevant (AI)MDD certificate(s) and the NB identification</i>
MOXYYY-C1 where: XX = gauge from 12 to 20 YYY = length from 80 mm to 300 mm	Ila	n/a REFs. are listed in 'Detailed list of MDD Ref. numbers', dated 2024/09/23, here attached.	Certificato / Certificate: G2 063838 0015 Rev.02 ON / NB: 0123
MOXYYY-K0 where: XX = gauge from 12 to 20 YYY = length from 80 mm to 300 mm	Ila	n/a REFs. are listed in 'Detailed list of MDD Ref. numbers', dated 2024/09/23, here attached.	Certificato / Certificate: G2 063838 0015 Rev.02 ON / NB: 0123
MOXYYY-K1 where: XX = gauge from 12 to 20 YYY = length from 80 mm to 300 mm	Ila	n/a REFs. are listed in 'Detailed list of MDD Ref. numbers', dated 2024/09/23, here attached.	Certificato / Certificate: G2 063838 0015 Rev.02 ON / NB: 0123
FCXYYYY-00 where: XX = gauge from 14 to 20 YYY = length from 80 mm to 300 mm	Ila	FCXYYYY-00 REFs. are listed in 'Detailed list of MDD Ref. numbers', dated 2024/09/23, here attached.	Certificato / Certificate: G2 063838 0015 Rev.02 ON / NB: 0123

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Table 1: Devices covered by this letter and for which IMQ S.p.A. is also responsible for appropriate surveillance of the corresponding devices under the (AI)MDD

Dispositivo (Nome o UDI-DI di base) oggetto della Domanda MDR <i>Device (Name or Basic UDI-DI) under MDR application</i>	Classificazione del Dispositivo oggetto della Domanda MDR <i>Classification of the device under MDR application</i> (1)	Se il dispositivo oggetto della Domanda MDR è un dispositivo sostitutivo, identificazione del corrispondente dispositivo (AI)MDD <i>If the device under MDR application is a substitute device, identification of the corresponding (AI)MDD device</i>	Riferimento del/i pertinente/i certificato/i (AI)MDD e identificazione dell'ON <i>Reference to relevant (AI)MDD certificate(s) and the NB identification</i>
FCXXYYY-01 where: XX = gauge from 14 to 20 YYY = length from 80 mm to 300 mm	Ila	FCXXYYY-01 REFs. are listed in 'Detailed list of MDD Ref. numbers', dated 2024/09/23, here attached.	Certificato / Certificate: G2 063838 0015 Rev.02 ON / NB: 0123
FCXXYYY-C0 where: XX = gauge from 14 to 20 YYY = length from 80 mm to 300 mm	Ila	FCXXYYY-C0 REFs. are listed in 'Detailed list of MDD Ref. numbers', dated 2024/09/23, here attached.	Certificato / Certificate: G2 063838 0015 Rev.02 ON / NB: 0123
FCXXYYY-C1 where: XX = gauge from 14 to 20 YYY = length from 80 mm to 300 mm	Ila	FCXXYYY-C1 REFs. are listed in 'Detailed list of MDD Ref. numbers', dated 2024/09/23, here attached.	Certificato / Certificate: G2 063838 0015 Rev.02 ON / NB: 0123
UNXXYYY-00 where: XX = gauge from 14 to 20 YYY = length from 80 mm to 300 mm	Ila	UNXXYYY-00 REFs. are listed in 'Detailed list of MDD Ref. numbers', dated 2024/09/23, here attached.	Certificato / Certificate: G2 063838 0015 Rev.02 ON / NB: 0123

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Table 1: Devices covered by this letter and for which IMQ S.p.A. is also responsible for appropriate surveillance of the corresponding devices under the (AI)MDD

Dispositivo (Nome o UDI-DI di base) oggetto della Domanda MDR <i>Device (Name or Basic UDI-DI) under MDR application</i>	Classificazione del Dispositivo oggetto della Domanda MDR <i>Classification of the device under MDR application</i> (1)	Se il dispositivo oggetto della Domanda MDR è un dispositivo sostitutivo, identificazione del corrispondente dispositivo (AI)MDD <i>If the device under MDR application is a substitute device, identification of the corresponding (AI)MDD device</i>	Riferimento del/i pertinente/i certificato/i (AI)MDD e identificazione dell'ON <i>Reference to relevant (AI)MDD certificate(s) and the NB identification</i>
UNXXYYY-01 where: XX = gauge from 14 to 20 YYY = length from 80 mm to 300 mm	Ila	UNXXYYY-01 REFs. are listed in 'Detailed list of MDD Ref. numbers', dated 2024/09/23, here attached.	Certificato / Certificate: G2 063838 0015 Rev.02 ON / NB: 0123
UNXXYYY-C0 where: XX = gauge from 14 to 20 YYY = length from 80 mm to 300 mm	Ila	UNXXYYY-C0 REFs. are listed in 'Detailed list of MDD Ref. numbers', dated 2024/09/23, here attached.	Certificato / Certificate: G2 063838 0015 Rev.02 ON / NB: 0123
UNXXYYY-C1 where: XX = gauge from 14 to 20 YYY = length from 80 mm to 300 mm	Ila	UNXXYYY-C1 REFs. are listed in 'Detailed list of MDD Ref. numbers', dated 2024/09/23, here attached.	Certificato / Certificate: G2 063838 0015 Rev.02 ON / NB: 0123
UCXXYYY-00 where: XX = gauge from 12 to 20 YYY = length from 80 mm to 300 mm	Ila	UCXXYYY-00 UPXXYYY-L0 REFs. are listed in 'Detailed list of MDD Ref. numbers', dated 2024/09/23, here attached.	Certificato / Certificate: G2 063838 0015 Rev.02 ON / NB: 0123

Tabella 1: Dispositivi oggetto della presente lettera e per i quali IMQ S.p.A. è anche responsabile dell'appropriata sorveglianza dei dispositivi corrispondenti ai sensi della (AI)MDD

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Dispositivo (Nome o UDI-DI di base) oggetto della Domanda MDR <i>Device (Name or Basic UDI-DI) under MDR application</i>	Classificazione del Dispositivo oggetto della Domanda MDR <i>Classification of the device under MDR application</i> (1)	Se il dispositivo oggetto della Domanda MDR è un dispositivo sostitutivo, identificazione del corrispondente dispositivo (AI)MDD <i>If the device under MDR application is a substitute device, identification of the corresponding (AI)MDD device</i>	Riferimento del/i pertinente/i certificato/i (AI)MDD e identificazione dell'ON <i>Reference to relevant (AI)MDD certificate(s) and the NB identification</i>
UCXXYYY-01 where: XX = gauge from 12 to 20 YYY = length from 80 mm to 300 mm	IIa	UCXXYYY-01 UPXXYYY-L1 REFs. are listed in 'Detailed list of MDD Ref. numbers', dated 2024/09/23, here attached.	Certificato / Certificate: G2 063838 0015 Rev.02 ON / NB: 0123
UCXXYYY-C0 where: XX = gauge from 12 to 20 YYY = length from 80 mm to 300 mm	IIa	UCXXYYY-C0 UPXXYYY-X0 REFs. are listed in 'Detailed list of MDD Ref. numbers', dated 2024/09/23, here attached.	Certificato / Certificate: G2 063838 0015 Rev.02 ON / NB: 0123
UCXXYYY-C1 where: XX = gauge from 12 to 20 YYY = length from 80 mm to 300 mm	IIa	UCXXYYY-C1 UPXXYYY-X1 REFs. are listed in 'Detailed list of MDD Ref. numbers', dated 2024/09/23, here attached.	Certificato / Certificate: G2 063838 0015 Rev.02 ON / NB: 0123
UCXXYYY-G0 where: XX = gauge from 12 to 20 YYY = length from 80 mm to 300 mm	IIa	n/a REFs. are listed in 'Detailed list of MDD Ref. numbers', dated 2024/09/23, here attached.	Certificato / Certificate: G2 063838 0015 Rev.02 ON / NB: 0123

<p>Tabella 1: Dispositivi oggetto della presente lettera e per i quali IMQ S.p.A. è anche responsabile dell'appropriata sorveglianza dei dispositivi corrispondenti ai sensi della (AI)MDD</p> <p><i>Table 1: Devices covered by this letter and for which IMQ S.p.A. is also responsible for appropriate surveillance of the corresponding devices under the (AI)MDD</i></p>			
<p>Dispositivo (Nome o UDI-DI di base) oggetto della Domanda MDR</p> <p><i>Device (Name or Basic UDI-DI) under MDR application</i></p>	<p>Classificazione del Dispositivo oggetto della Domanda MDR</p> <p><i>Classification of the device under MDR application</i></p> <p>(1)</p>	<p>Se il dispositivo oggetto della Domanda MDR è un dispositivo sostitutivo, identificazione del corrispondente dispositivo (AI)MDD</p> <p><i>If the device under MDR application is a substitute device, identification of the corresponding (AI)MDD device</i></p>	<p>Riferimento del/i pertinente/i certificato/i (AI)MDD e identificazione dell'ON</p> <p><i>Reference to relevant (AI)MDD certificate(s) and the NB identification</i></p>
<p>UCXXYYY-G1</p> <p>where: XX = gauge from 12 to 20 YYY = length from 80 mm to 300 mm</p>	Ila	<p>n/a</p> <p>REFs. are listed in 'Detailed list of MDD Ref. numbers', dated 2024/09/23, here attached.</p>	<p>Certificato / Certificate: G2 063838 0015 Rev.02 ON / NB: 0123</p>
<p>UCXXYYY-F0</p> <p>where: XX = gauge from 12 to 20 YYY = length from 80 mm to 300 mm</p>	Ila	<p>n/a</p> <p>REFs. are listed in 'Detailed list of MDD Ref. numbers', dated 2024/09/23, here attached.</p>	<p>Certificato / Certificate: G2 063838 0015 Rev.02 ON / NB: 0123</p>
<p>UCXXYYY-F1</p> <p>where: XX = gauge from 12 to 20 YYY = length from 80 mm to 300 mm</p>	Ila	<p>n/a</p> <p>REFs. are listed in 'Detailed list of MDD Ref. numbers', dated 2024/09/23, here attached.</p>	<p>Certificato / Certificate: G2 063838 0015 Rev.02 ON / NB: 0123</p>
<p>ULXYYYY-C0</p> <p>where: XX = gauge from 12 to 20 YYY = length from 80 mm to 300 mm</p>	Ila	<p>ULXYYYY-C0 UCXXYYY-E0 UPXYYYY-Z0</p> <p>REFs. are listed in 'Detailed list of MDD Ref. numbers', dated 2024/09/23, here attached.</p>	<p>Certificato / Certificate: G2 063838 0015 Rev.02 ON / NB: 0123</p>

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Dispositivo (Nome o UDI-DI di base) oggetto della Domanda MDR Device (Name or Basic UDI-DI) under MDR application	Classificazione del Dispositivo oggetto della Domanda MDR Classification of the device under MDR application (1)	Se il dispositivo oggetto della Domanda MDR è un dispositivo sostitutivo, identificazione del corrispondente dispositivo (AI)MDD If the device under MDR application is a substitute device, identification of the corresponding (AI)MDD device	Riferimento del/i pertinente/i certificato/i (AI)MDD e identificazione dell'ON Reference to relevant (AI)MDD certificate(s) and the NB identification
ULXYYYY-C1 where: XX = gauge from 12 to 20 YYY = length from 80 mm to 300 mm	IIa	ULXYYYY-C1 UCXYYYY-E1 UPXYYYY-Z1 REFs. are listed in 'Detailed list of MDD Ref. numbers', dated 2024/09/23, here attached.	Certificato / Certificate: G2 063838 0015 Rev.02 ON / NB: 0123
ULXYYYY-00 where: XX = gauge from 12 to 20 YYY = length from 80 mm to 300 mm	IIa	ULXYYYY-00 UCXYYYY-S0 UPXYYYY-S0 REFs. are listed in 'Detailed list of MDD Ref. numbers', dated 2024/09/23, here attached.	Certificato / Certificate: G2 063838 0015 Rev.02 ON / NB: 0123
ULXYYYY-01 where: XX = gauge from 12 to 20 YYY = length from 80 mm to 300 mm	IIa	ULXYYYY-01 UCXYYYY-S1 UPXYYYY-S1 REFs. are listed in 'Detailed list of MDD Ref. numbers', dated 2024/09/23, here attached.	Certificato / Certificate: G2 063838 0015 Rev.02 ON / NB: 0123
UGXYYYY-00 XX = gauge from 12 to 20 YYY = length from 80 mm to 300 mm	IIa	n/a REFs. are listed in 'Detailed list of MDD Ref. numbers', dated 2024/09/23, here attached.	Certificato / Certificate: G2 063838 0015 Rev.02 ON / NB: 0123

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Dispositivo (Nome o UDI-DI di base) oggetto della Domanda MDR <i>Device (Name or Basic UDI-DI) under MDR application</i>	Classificazione del Dispositivo oggetto della Domanda MDR <i>Classification of the device under MDR application</i> (1)	Se il dispositivo oggetto della Domanda MDR è un dispositivo sostitutivo, identificazione del corrispondente dispositivo (AI)MDD <i>If the device under MDR application is a substitute device, identification of the corresponding (AI)MDD device</i>	Riferimento del/i pertinente/i certificato/i (AI)MDD e identificazione dell'ON <i>Reference to relevant (AI)MDD certificate(s) and the NB identification</i>
UGXXYYY-01 XX = gauge from 12 to 20 YYY = length from 80 mm to 300 mm	Ila	n/a REFs. are listed in 'Detailed list of MDD Ref. numbers', dated 2024/09/23, here attached.	Certificato / <i>Certificate:</i> G2 063838 0015 Rev.02 ON / NB: 0123
UGXXYYY-C0 XX = gauge from 12 to 20 YYY = length from 80 mm to 300 mm	Ila	n/a REFs. are listed in 'Detailed list of MDD Ref. numbers', dated 2024/09/23, here attached.	Certificato / <i>Certificate:</i> G2 063838 0015 Rev.02 ON / NB: 0123
UGXXYYY-C1 XX = gauge from 12 to 20 YYY = length from 80 mm to 300 mm	Ila	n/a REFs. are listed in 'Detailed list of MDD Ref. numbers', dated 2024/09/23, here attached.	Certificato / <i>Certificate:</i> G2 063838 0015 Rev.02 ON / NB: 0123
UTXXYYY-00 XX = gauge from 12 to 20 YYY = length from 80 mm to 300 mm	Ila	n/a REFs. are listed in 'Detailed list of MDD Ref. numbers', dated 2024/09/23, here attached.	Certificato / <i>Certificate:</i> G2 063838 0015 Rev.02 ON / NB: 0123
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UTXYYYY-C1 XX = gauge from 12 to 20 YYY = length from 80 mm to 300 mm	Ila	n/a REFs. are listed in 'Detailed list of MDD Ref. numbers', dated 2024/09/23, here attached.	Certificato / <i>Certificate:</i> G2 063838 0015 Rev.02 ON / NB: 0123
UMXYYYY-00 XX = gauge from 12 to 20 YYY = length from 80 mm to 300 mm	Ila	n/a REFs. are listed in 'Detailed list of MDD Ref. numbers', dated 2024/09/23, here attached.	Certificato / <i>Certificate:</i> G2 063838 0015 Rev.02 ON / NB: 0123
UMXYYYY-01 XX = gauge from 12 to 20 YYY = length from 80 mm to 300 mm	Ila	n/a REFs. are listed in 'Detailed list of MDD Ref. numbers', dated 2024/09/23, here attached.	Certificato / <i>Certificate:</i> G2 063838 0015 Rev.02 ON / NB: 0123
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UMXXYYY-C1 XX = gauge from 12 to 20 YYY = length from 80 mm to 300 mm	Ila	n/a REFs. are listed in 'Detailed list of MDD Ref. numbers', dated 2024/09/23, here attached.	Certificato / Certificate: G2 063838 0015 Rev.02 ON / NB: 0123
UFXXYYY-00 XX = gauge from 14 to 20 YYY = length from 80 mm to 300 mm	Ila	UFXXYYY-00 UNXXYYY-F0 REFs. are listed in 'Detailed list of MDD Ref. numbers', dated 2024/09/23, here attached.	Certificato / Certificate: G2 063838 0015 Rev.02 ON / NB: 0123
UFXXYYY-01 XX = gauge from 14 to 20 YYY = length from 80 mm to 300 mm	Ila	UFXXYYY-01 UNXXYYY-F1 REFs. are listed in 'Detailed list of MDD Ref. numbers', dated 2024/09/23, here attached.	Certificato / Certificate: G2 063838 0015 Rev.02 ON / NB: 0123
UFXXYYY-C0 XX = gauge from 14 to 20 YYY = length from 80 mm to 300 mm	Ila	UFXXYYY-C0 UNXXYYY-X0 REFs. are listed in 'Detailed list of MDD Ref. numbers', dated 2024/09/23, here attached.	Certificato / Certificate: G2 063838 0015 Rev.02 ON / NB: 0123
UFXXYYY-C1 XX = gauge from 14 to 20 YYY = length from 80 mm to 300 mm	Ila	UFXXYYY-C1 UNXXYYY-X1 REFs. are listed in 'Detailed list of MDD Ref. numbers', dated 2024/09/23, here attached.	Certificato / Certificate: G2 063838 0015 Rev.02 ON / NB: 0123

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Dispositivo (Nome o UDI-DI di base) oggetto della Domanda MDR <i>Device (Name or Basic UDI-DI) under MDR application</i>	Classificazione del Dispositivo oggetto della Domanda MDR <i>Classification of the device under MDR application</i> (1)	Se il dispositivo oggetto della Domanda MDR è un dispositivo sostitutivo, identificazione del corrispondente dispositivo (AI)MDD <i>If the device under MDR application is a substitute device, identification of the corresponding (AI)MDD device</i>	Riferimento del/i pertinente/i certificato/i (AI)MDD e identificazione dell'ON <i>Reference to relevant (AI)MDD certificate(s) and the NB identification</i>
UHXXYYY-00 XX = gauge from 12 to 20 YYY = length from 80 mm to 300 mm	IIa	UHXXYYY-00 UDXXYYY-0H REFs. are listed in 'Detailed list of MDD Ref. numbers', dated 2024/09/23, here attached.	Certificato / Certificate: G2 063838 0015 Rev.02 ON / NB: 0123
UHXXYYY-01 XX = gauge from 12 to 20 YYY = length from 80 mm to 300 mm	IIa	UHXXYYY-01 UDXXYYY-1H REFs. are listed in 'Detailed list of MDD Ref. numbers', dated 2024/09/23, here attached.	Certificato / Certificate: G2 063838 0015 Rev.02 ON / NB: 0123
UHXXYYY-C0 XX = gauge from 12 to 20 YYY = length from 80 mm to 300 mm	IIa	UHXXYYY-C0 UDXXYYY-CH REFs. are listed in 'Detailed list of MDD Ref. numbers', dated 2024/09/23, here attached.	Certificato / Certificate: G2 063838 0015 Rev.02 ON / NB: 0123
UHXXYYY-C1 XX = gauge from 12 to 20 YYY = length from 80 mm to 300 mm	IIa	UHXXYYY-C1 UDXXYYY-TH REFs. are listed in 'Detailed list of MDD Ref. numbers', dated 2024/09/23, here attached.	Certificato / Certificate: G2 063838 0015 Rev.02 ON / NB: 0123
CMXXYYY-00 XX = gauge from 12 to 20 YYY = length from 80 mm to 300 mm	IIa	n/a REFs. are listed in 'Detailed list of MDD Ref. numbers', dated 2024/09/23, here attached.	Certificato / Certificate: G2 063838 0015 Rev.02 ON / NB: 0123

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Dispositivo (Nome o UDI-DI di base) oggetto della Domanda MDR <i>Device (Name or Basic UDI-DI) under MDR application</i>	Classificazione del Dispositivo oggetto della Domanda MDR <i>Classification of the device under MDR application</i> (1)	Se il dispositivo oggetto della Domanda MDR è un dispositivo sostitutivo, identificazione del corrispondente dispositivo (AI)MDD <i>If the device under MDR application is a substitute device, identification of the corresponding (AI)MDD device</i>	Riferimento del/i pertinente/i certificato/i (AI)MDD e identificazione dell'ON <i>Reference to relevant (AI)MDD certificate(s) and the NB identification</i>
CMXXYYY-10 XX = gauge from 12 to 20 YYY = length from 80 mm to 300 mm	Ia	n/a REFs. are listed in 'Detailed list of MDD Ref. numbers', dated 2024/09/23, here attached.	Certificato / <i>Certificate:</i> G2 063838 0015 Rev.02 ON / NB: 0123
CMXXYYY-0S XX = gauge from 12 to 20 YYY = length from 80 mm to 300 mm	Ia	n/a REFs. are listed in 'Detailed list of MDD Ref. numbers', dated 2024/09/23, here attached.	Certificato / <i>Certificate:</i> G2 063838 0015 Rev.02 ON / NB: 0123
CMXXYYY-1S XX = gauge from 12 to 20 YYY = length from 80 mm to 300 mm	Ia	n/a REFs. are listed in 'Detailed list of MDD Ref. numbers', dated 2024/09/23, here attached.	Certificato / <i>Certificate:</i> G2 063838 0015 Rev.02 ON / NB: 0123
COXXYYY-00 XX = gauge from 12 to 20 YYY = length from 80 mm to 300 mm	Ia	n/a REFs. are listed in 'Detailed list of MDD Ref. numbers', dated 2024/09/23, here attached.	Certificato / <i>Certificate:</i> G2 063838 0015 Rev.02 ON / NB: 0123
COXXYYY-10 XX = gauge from 12 to 20 YYY = length from 80 mm to 300 mm	Ia	n/a REFs. are listed in 'Detailed list of MDD Ref. numbers', dated 2024/09/23, here attached.	Certificato / <i>Certificate:</i> G2 063838 0015 Rev.02 ON / NB: 0123

Tabella 1: Dispositivi oggetto della presente lettera e per i quali IMQ S.p.A. è anche responsabile dell'appropriata sorveglianza dei dispositivi corrispondenti ai sensi della (AI)MDD Table 1: Devices covered by this letter and for which IMQ S.p.A. is also responsible for appropriate surveillance of the corresponding devices under the (AI)MDD			
Dispositivo (Nome o UDI-DI di base) oggetto della Domanda MDR Device (Name or Basic UDI-DI) under MDR application	Classificazione del Dispositivo oggetto della Domanda MDR Classification of the device under MDR application (1)	Se il dispositivo oggetto della Domanda MDR è un dispositivo sostitutivo, identificazione del corrispondente dispositivo (AI)MDD If the device under MDR application is a substitute device, identification of the corresponding (AI)MDD device	Riferimento del/i pertinente/i certificato/i (AI)MDD e identificazione dell'ON Reference to relevant (AI)MDD certificate(s) and the NB identification
CEXYYYY-00 XX = gauge from 12 to 20 YYY = length from 60 mm to 300 mm	Ila	CEXYYYY-00 REFs. are listed in 'Detailed list of MDD Ref. numbers', dated 2024/09/23, here attached.	Certificato / Certificate: G2 063838 0015 Rev.02 ON / NB: 0123
CEXYYYY-10 XX = gauge from 12 to 20 YYY = length from 60 mm to 300 mm	Ila	CEXYYYY-10 REFs. are listed in 'Detailed list of MDD Ref. numbers', dated 2024/09/23, here attached.	Certificato / Certificate: G2 063838 0015 Rev.02 ON / NB: 0123
CBXYYYY-00 XX = gauge from 12 to 20 YYY = length from 80 mm to 300 mm	Ila	CBXYYYY-00 REFs. are listed in 'Detailed list of MDD Ref. numbers', dated 2024/09/23, here attached.	Certificato / Certificate: G2 063838 0015 Rev.02 ON / NB: 0123
CBXYYYY-10 XX = gauge from 12 to 20 YYY = length from 80 mm to 300 mm	Ila	CBXYYYY-10 REFs. are listed in 'Detailed list of MDD Ref. numbers', dated 2024/09/23, here attached.	Certificato / Certificate: G2 063838 0015 Rev.02 ON / NB: 0123
CVXYYYY-00 XX = gauge from 14 to 20 YYY = length from 80 mm to 300 mm	Ila	CVXYYYY-00 REFs. are listed in 'Detailed list of MDD Ref. numbers', dated 2024/09/23, here attached.	Certificato / Certificate: G2 063838 0015 Rev.02 ON / NB: 0123

Tabella 1: Dispositivi oggetto della presente lettera e per i quali IMQ S.p.A. è anche responsabile dell'appropriata sorveglianza dei dispositivi corrispondenti ai sensi della (AI)MDD

Table 1: Devices covered by this letter and for which IMQ S.p.A. is also responsible for appropriate surveillance of the corresponding devices under the (AI)MDD

Dispositivo (Nome o UDI-DI di base) oggetto della Domanda MDR <i>Device (Name or Basic UDI-DI) under MDR application</i>	Classificazione del Dispositivo oggetto della Domanda MDR <i>Classification of the device under MDR application</i> (1)	Se il dispositivo oggetto della Domanda MDR è un dispositivo sostitutivo, identificazione del corrispondente dispositivo (AI)MDD <i>If the device under MDR application is a substitute device, identification of the corresponding (AI)MDD device</i>	Riferimento del/i pertinente/i certificato/i (AI)MDD e identificazione dell'ON <i>Reference to relevant (AI)MDD certificate(s) and the NB identification</i>
CVXXYYY-10 XX = gauge from 14 to 20 YYY = length from 80 mm to 300 mm	Ila	CVXXYYY-10 REFs. are listed in 'Detailed list of MDD Ref. numbers', dated 2024/09/23, here attached.	Certificato / <i>Certificate:</i> G2 063838 0015 Rev.02 ON / NB: 0123
CFXYYYY-00 XX = gauge from 14 to 20 YYY = length from 80 mm to 300 mm	Ila	CFXYYYY-00 REFs. are listed in 'Detailed list of MDD Ref. numbers', dated 2024/09/23, here attached.	Certificato / <i>Certificate:</i> G2 063838 0015 Rev.02 ON / NB: 0123
CTXYYYY-00 where: <ul style="list-style-type: none"> XX = gauge from 12 to 16 and 20 YYY = length from 60 to 200 mm XX = gauge 18 YYY = length from 60 mm to 250 mm 	Ila	CTXYYYY-00 REFs. are listed in 'Detailed list of MDD Ref. numbers', dated 2024/09/23, here attached.	Certificato / <i>Certificate:</i> G2 063838 0015 Rev.02 ON / NB: 0123

<p>Tabella 1: Dispositivi oggetto della presente lettera e per i quali IMQ S.p.A. è anche responsabile dell'appropriata sorveglianza dei dispositivi corrispondenti ai sensi della (AI)MDD</p> <p><i>Table 1: Devices covered by this letter and for which IMQ S.p.A. is also responsible for appropriate surveillance of the corresponding devices under the (AI)MDD</i></p>			
<p>Dispositivo (Nome o UDI-DI di base) oggetto della Domanda MDR</p> <p><i>Device (Name or Basic UDI-DI) under MDR application</i></p>	<p>Classificazione del Dispositivo oggetto della Domanda MDR</p> <p><i>Classification of the device under MDR application</i></p> <p>(1)</p>	<p>Se il dispositivo oggetto della Domanda MDR è un dispositivo sostitutivo, identificazione del corrispondente dispositivo (AI)MDD</p> <p><i>If the device under MDR application is a substitute device, identification of the corresponding (AI)MDD device</i></p>	<p>Riferimento del/i pertinente/i certificato/i (AI)MDD e identificazione dell'ON</p> <p><i>Reference to relevant (AI)MDD certificate(s) and the NB identification</i></p>
<p>CTXXYYY-10</p> <p>where:</p> <ul style="list-style-type: none"> XX = gauge from 12 to 16 and 20 YYY = length from 60 to 200 mm XX = gauge 18 YYY = length from 60 mm to 250 mm 	IIa	<p>CTXXYYY-10</p> <p>REFs. are listed in 'Detailed list of MDD Ref. numbers', dated 2024/09/23, here attached.</p>	<p>Certificato / Certificate: G2 063838 0015 Rev.02</p> <p>ON / NB: 0123</p>
<p>CXXXYYY-00</p> <p>XX = gauge from 11 to 19</p> <p>YYY = length from 30 mm to 250 mm</p>	IIa	<p>n/a</p> <p>REFs. are listed in 'Detailed list of MDD Ref. numbers', dated 2024/09/23, here attached.</p>	<p>Certificato / Certificate: G2 063838 0015 Rev.02</p> <p>ON / NB: 0123</p>
<p>CXXXYYY-10</p> <p>XX = gauge from 11 to 19</p> <p>YYY = length from 30 mm to 250 mm</p>	IIa	<p>n/a</p> <p>REFs. are listed in 'Detailed list of MDD Ref. numbers', dated 2024/09/23, here attached.</p>	<p>Certificato / Certificate: G2 063838 0015 Rev.02</p> <p>ON / NB: 0123</p>
<p>CUXXYYY-00</p> <p>XX = gauge from 12 to 20</p> <p>YYY = length from 80 mm to 300 mm</p>	IIa	<p>n/a</p> <p>REFs. are listed in 'Detailed list of MDD Ref. numbers', dated 2024/09/23, here attached.</p>	<p>Certificato / Certificate: G2 063838 0015 Rev.02</p> <p>ON / NB: 0123</p>

Tabella 1: Dispositivi oggetto della presente lettera e per i quali IMQ S.p.A. è anche responsabile dell'appropriata sorveglianza dei dispositivi corrispondenti ai sensi della (AI)MDD Table 1: Devices covered by this letter and for which IMQ S.p.A. is also responsible for appropriate surveillance of the corresponding devices under the (AI)MDD			
Dispositivo (Nome o UDI-DI di base) oggetto della Domanda MDR Device (Name or Basic UDI-DI) under MDR application	Classificazione del Dispositivo oggetto della Domanda MDR Classification of the device under MDR application (1)	Se il dispositivo oggetto della Domanda MDR è un dispositivo sostitutivo, identificazione del corrispondente dispositivo (AI)MDD If the device under MDR application is a substitute device, identification of the corresponding (AI)MDD device	Riferimento del/i pertinente/i certificato/i (AI)MDD e identificazione dell'ON Reference to relevant (AI)MDD certificate(s) and the NB identification
CUXYYYY-10 XX = gauge from 12 to 20 YYY = length from 80 mm to 300 mm	Ila	n/a REFs. are listed in 'Detailed list of MDD Ref. numbers', dated 2024/09/23, here attached.	Certificato / Certificate: G2 063838 0015 Rev.02 ON / NB: 0123
Device for pre-operative localisation of non-palpable lesions of the breast:			
XWXXYYY-00 XX = gauge from 20 to 21 YYY = length from 60 mm to 160 mm	Ila	XWXXYYY-0S SRXXYYY-00 REFs. are listed in 'Detailed list of MDD Ref. numbers', dated 2024/09/23, here attached.	Certificato / Certificate: G2 063838 0015 Rev.02 ON / NB: 0123
XWXXYYY-01 XX = gauge from 20 to 21 YYY = length from 60 mm to 160 mm	Ila	XWXXYYY-1S SRXXYYY-02 REFs. are listed in 'Detailed list of MDD Ref. numbers', dated 2024/09/23, here attached.	Certificato / Certificate: G2 063838 0015 Rev.02 ON / NB: 0123
XWXXYYY-02 XX = gauge from 20 to 21 YYY = length from 60 mm to 160 mm	Ila	XWXXYYY-2S SRXXYYY-03 REFs. are listed in 'Detailed list of MDD Ref. numbers', dated 2024/09/23, here attached.	Certificato / Certificate: G2 063838 0015 Rev.02 ON / NB: 0123

<p>Tabella 1: Dispositivi oggetto della presente lettera e per i quali IMQ S.p.A. è anche responsabile dell'appropriata sorveglianza dei dispositivi corrispondenti ai sensi della (AI)MDD</p> <p><i>Table 1: Devices covered by this letter and for which IMQ S.p.A. is also responsible for appropriate surveillance of the corresponding devices under the (AI)MDD</i></p>			
<p>Dispositivo (Nome o UDI-DI di base) oggetto della Domanda MDR</p> <p><i>Device (Name or Basic UDI-DI) under MDR application</i></p>	<p>Classificazione del Dispositivo oggetto della Domanda MDR</p> <p><i>Classification of the device under MDR application</i></p> <p>(1)</p>	<p>Se il dispositivo oggetto della Domanda MDR è un dispositivo sostitutivo, identificazione del corrispondente dispositivo (AI)MDD</p> <p><i>If the device under MDR application is a substitute device, identification of the corresponding (AI)MDD device</i></p>	<p>Riferimento del/i pertinente/i certificato/i (AI)MDD e identificazione dell'ON</p> <p><i>Reference to relevant (AI)MDD certificate(s) and the NB identification</i></p>
<p>XWXXYYY-00</p> <p>XX = gauge 20 YYY = length from 60 mm to 120 mm</p>	IIa	<p>n/a</p> <p>REFs. are listed in 'Detailed list of MDD Ref. numbers', dated 2024/09/23, here attached.</p>	<p>Certificato / Certificate: G2 063838 0015 Rev.02 ON / NB: 0123</p>
<p>XWXXYYY-0J</p> <p>XX = gauge 20 YYY = length from 30 mm to 100 mm</p>	IIa	<p>n/a</p> <p>REFs. are listed in 'Detailed list of MDD Ref. numbers', dated 2024/09/23, here attached.</p>	<p>Certificato / Certificate: G2 063838 0015 Rev.02 ON / NB: 0123</p>
<p>Resusable biopsy guns:</p>			
<p>MEDGUN-00/N</p>	IIa	n/a	<p>Certificato / Certificate: G2 063838 0015 Rev.02 ON / NB: 0123</p>
<p>MEDCORE-00/N</p>	IIa	n/a	<p>Certificato / Certificate: G2 063838 0015 Rev.02 ON / NB: 0123</p>
<p>M-GUN-00/N</p>	IIa	n/a	<p>Certificato / Certificate: G2 063838 0015 Rev.02 ON / NB: 0123</p>

Tabella 1: Dispositivi oggetto della presente lettera e per i quali IMQ S.p.A. è anche responsabile dell'appropriata sorveglianza dei dispositivi corrispondenti ai sensi della (AI)MDD Table 1: Devices covered by this letter and for which IMQ S.p.A. is also responsible for appropriate surveillance of the corresponding devices under the (AI)MDD			
Dispositivo (Nome o UDI-DI di base) oggetto della Domanda MDR Device (Name or Basic UDI-DI) under MDR application	Classificazione del Dispositivo oggetto della Domanda MDR Classification of the device under MDR application (1)	Se il dispositivo oggetto della Domanda MDR è un dispositivo sostitutivo, identificazione del corrispondente dispositivo (AI)MDD If the device under MDR application is a substitute device, identification of the corresponding (AI)MDD device	Riferimento del/i pertinente/i certificato/i (AI)MDD e identificazione dell'ON Reference to relevant (AI)MDD certificate(s) and the NB identification
Thoracentesis and paracentesis kits:			
PR00005-00 PR00008-00 PR00012-00 PR55005-00 PR55008-00 PR55012-00 PR80005-00 PR80008-00 PR80012-00	Ila	n/a	Certificato / Certificate: G2 063838 0015 Rev.02 ON / NB: 0123
PR00002-00	Ila	PR00002-00 TR00200-00	Certificato / Certificate: G2 063838 0015 Rev.02 ON / NB: 0123
PR55002-00	Ila	PR55002-00 TR55200-00	Certificato / Certificate: G2 063838 0015 Rev.02 ON / NB: 0123

Tabella 1: Dispositivi oggetto della presente lettera e per i quali IMQ S.p.A. è anche responsabile dell'appropriata sorveglianza dei dispositivi corrispondenti ai sensi della (AI)MDD Table 1: Devices covered by this letter and for which IMQ S.p.A. is also responsible for appropriate surveillance of the corresponding devices under the (AI)MDD			
Dispositivo (Nome o UDI-DI di base) oggetto della Domanda MDR Device (Name or Basic UDI-DI) under MDR application	Classificazione del Dispositivo oggetto della Domanda MDR Classification of the device under MDR application (1)	Se il dispositivo oggetto della Domanda MDR è un dispositivo sostitutivo, identificazione del corrispondente dispositivo (AI)MDD If the device under MDR application is a substitute device, identification of the corresponding (AI)MDD device	Riferimento del/i pertinente/i certificato/i (AI)MDD e identificazione dell'ON Reference to relevant (AI)MDD certificate(s) and the NB identification
PR80002-00	Ila	PR80002-00 TR80200-00	Certificato / Certificate: G2 063838 0015 Rev.02 ON / NB: 0123
TR80200-10 TR00200-10 TR55200-10	Ila	n/a	Certificato / Certificate: G2 063838 0015 Rev.02 ON / NB: 0123
Veress needles:			
VR14100-00 VR14120-00 VR14150-00 VR15100-00 VR15120-00 VR15150-00 VR16100-00 VR16120-00 VR16150-00 VR14100-10 VR14120-10 VR14150-10	Ila	n/a	Certificato / Certificate: G2 063838 0015 Rev.02 ON / NB: 0123

Tabella 1: Dispositivi oggetto della presente lettera e per i quali IMQ S.p.A. è anche responsabile dell'appropriata sorveglianza dei dispositivi corrispondenti ai sensi della (AI)MDD Table 1: Devices covered by this letter and for which IMQ S.p.A. is also responsible for appropriate surveillance of the corresponding devices under the (AI)MDD			
Dispositivo (Nome o UDI-DI di base) oggetto della Domanda MDR Device (Name or Basic UDI-DI) under MDR application	Classificazione del Dispositivo oggetto della Domanda MDR Classification of the device under MDR application (1)	Se il dispositivo oggetto della Domanda MDR è un dispositivo sostitutivo, identificazione del corrispondente dispositivo (AI)MDD If the device under MDR application is a substitute device, identification of the corresponding (AI)MDD device	Riferimento del/i pertinente/i certificato/i (AI)MDD e identificazione dell'ON Reference to relevant (AI)MDD certificate(s) and the NB identification
VR15100-10 VR15120-10 VR15150-10 VR16100-10 VR16120-10 VR16150-10 VR14100-20 VR14120-20 VR14150-20 VR15100-20 VR15120-20 VR15150-20 VR16100-20 VR16120-20 VR16150-20 VR14100-02 VR14120-02 VR14150-02 VR15100-02 VR15120-02 VR15150-02			

<p>Tabella 1: Dispositivi oggetto della presente lettera e per i quali IMQ S.p.A. è anche responsabile dell'appropriata sorveglianza dei dispositivi corrispondenti ai sensi della (AI)MDD</p> <p><i>Table 1: Devices covered by this letter and for which IMQ S.p.A. is also responsible for appropriate surveillance of the corresponding devices under the (AI)MDD</i></p>			
<p>Dispositivo (Nome o UDI-DI di base) oggetto della Domanda MDR</p> <p><i>Device (Name or Basic UDI-DI) under MDR application</i></p>	<p>Classificazione del Dispositivo oggetto della Domanda MDR</p> <p><i>Classification of the device under MDR application</i></p> <p>(1)</p>	<p>Se il dispositivo oggetto della Domanda MDR è un dispositivo sostitutivo, identificazione del corrispondente dispositivo (AI)MDD</p> <p><i>If the device under MDR application is a substitute device, identification of the corresponding (AI)MDD device</i></p>	<p>Riferimento del/i pertinente/i certificato/i (AI)MDD e identificazione dell'ON</p> <p><i>Reference to relevant (AI)MDD certificate(s) and the NB identification</i></p>
<p>VR16100-02</p> <p>VR16120-02</p> <p>VR16150-02</p> <p>VR14100-12</p> <p>VR14120-12</p> <p>VR14150-12</p> <p>VR15100-12</p> <p>VR15120-12</p> <p>VR15150-12</p> <p>VR16100-12</p> <p>VR16120-12</p> <p>VR16150-12</p> <p>VR14100-22</p> <p>VR14120-22</p> <p>VR14150-22</p> <p>VR15100-22</p> <p>VR15120-22</p> <p>VR15150-22</p> <p>VR16100-22</p> <p>VR16120-22</p> <p>VR16150-22</p>			

Tabella 2: Dispositivi oggetto della presente lettera e per i quali IMQ S.p.A. <u>non</u> è responsabile dell'appropriata sorveglianza dei dispositivi corrispondenti ai sensi della (AI)MDD Table 2: Devices covered by this letter and for which IMQ S.p.A. is <u>not</u> responsible for appropriate surveillance of the corresponding devices under the (AI)MDD			
Dispositivo (Nome o UDI-DI di base) oggetto della Domanda MDR Device (Name or Basic UDI-DI) under MDR application	Classificazione del Dispositivo oggetto della Domanda MDR Classification of the device under MDR application <i>(1)</i>	Se il dispositivo oggetto della Domanda MDR è un dispositivo sostitutivo, identificazione del corrispondente dispositivo (AI)MDD If the device under MDR application is a substitute device, identification of the corresponding (AI)MDD device	Riferimento del/i pertinente/i certificato/i (AI)MDD e identificazione dell'ON Reference to relevant (AI)MDD certificate(s) and the NB identification
n/a	n/a	n/a	n/a

¹ Classificazione del dispositivo oggetto della Domanda MDR proposta dal fabbricante ai sensi dell'Al. VIII del MDR e verificata in via preliminare dall'ON ai sensi della sezione 4.2 (d) dell'Allegato VII del MDR / Classification of the device under MDR application, as proposed by the manufacturer according to Annex VIII of the MDR and preliminary verified by the NB according to Section 4.2 (d) of Annex VII of the MDR

Tabella 3: Storico delle revisioni della presente lettera di conferma Table 3: Revision history of this confirmation letter		
Data / Date	N. di protocollo / Protocol No.	Azione / Action
2024/05/17	FP-2988/24-nc10	Prima emissione / First issue
2024/06/01	FP-3366/24-nc10	Correzione errore digitazione e aggiunta dei dispositivi VR16120-20 e VR16150-20 alla Tabella 2/ Misprint correction and addition of devices VR16120-20 and VR16150-20 to Table 2
2024/09/26	FP-5637/24-fg10	<p>Spostamento dei dispositivi dalla Tabella 2 alla Tabella 1 / Moving devices from Table 2 to Table 1.</p> <p>Inserimento, in allegato alla presente, del doc. 'REFs. are listed in 'Detailed list of MDD Ref. numbers' del 2024/09/23, in accordo al Transfer Agreement / Enclosed herewith the 'REFs. are listed in 'Detailed list of MDD Ref. numbers' of 2024/09/23, in accordance with the Transfer Agreement.</p>

Na każdej stronie logo **IMQ**

(Str1)

Nr protokołu: FP-5637/24-FG10

Data: 2024/09/26

List potwierdzający jednostki notyfikowanej

Nr. ref. 1002C07224522C_CL

Do wszystkich zainteresowanych:

Potwierdzenie statusu formalnego wniosku, pisemnej umowy i odpowiedniego nadzoru w ramach rozporządzenia (UE)2023/607 zmieniającego rozporządzenia (UE) 2017/745 i 2017/746 w odniesieniu do przepisów przejściowych dotyczących niektórych wyrobów medycznych i wyrobów medycznych do diagnostyki in vitro.

Niniejsze pismo potwierdza, że **IMQ S.p.A.**, spółka działająca na podstawie Rozporządzenia (UE) 2017/745 (MDR) i oznaczona numerem 0051 w NANDO, otrzymała formalny wniosek zgodnie z sekcją 4.3 akapit pierwszy załącznika VII do MDR oraz podpisała pisemną umowę zgodnie z sekcją akapit drugi załącznika VII do MDR z następującym producentem:

MEDAX SRL Unipersonale

VIA R. PIVA 1/A - 46025 POGGIO RUSCO (MN)

SRN: IT-MF-000024882

*(w stopce dane biznesowe i bankowe firmy **IMQS.p.A.**)*

(Str2)

Wyroby objęte formalnym wnioskiem i pisemną umową, o których mowa powyżej zostały określone w poniższych tabelach a w szczególności:

- Tabela 1 określa wyroby, dla których **IMQ S.p.A.** otrzymała formalny wniosek MDR, zawarła pisemną umowę i jest również odpowiedzialna za odpowiedni nadzór nad odpowiednimi wyrobami zgodnie z Dyrektywą 90/385/EWG lub Dyrektywą 93/42/EWG dalej: (AI) MDD.

- Tabela 2 określa wyroby, dla których IMQ S.p.A. otrzymała formalny wniosek MDR, zawarła pisemną umowę, ale nie wzięła na siebie odpowiedzialności za właściwy nadzór nad odpowiednimi wyrobami na mocy (AI)MDD.

W przypadku wyrobów objętych certyfikatami wydanymi na podstawie (AI) MDD (zwanymi dalej „certyfikatami (AI)MDD”), których termin ważności upłynął po dniu 26 maja 2021 r. i przed dniem 20 marca 2023 r. a które nie zostały wcześniej wycofane, niniejsze pismo potwierdza również, że producent podpisał pisemną umowę na podstawie MDR przed datą wygaśnięcia odpowiedniego certyfikatu (AI)MDD lub dostarczył dowód, że właściwy organ państwa członkowskiego przyznał dla odpowiednich wyrobów odstępstwo lub zwolnienie od obowiązującej procedury oceny zgodności zgodnie z art. 59 ust. 1 MDR lub odpowiednio art. 97 ust. 1 MDR, do dnia 20 marca 2023 r.

(Str3)

Terminy przejściowe, które mają zastosowanie do wyrobów objęte niniejszym pismem, z zastrzeżeniem ciągłej zgodności producenta z innymi warunkami określonymi w art. 120 (3c) MDR (zmienionego rozporządzeniem (UE) 2023/607) przedstawiono poniżej:

- a) 31 grudnia 2027 r. dla wszystkich wyrobów klasy IIi oraz dla wyrobów do implantacji klasy IIb z wyłączeniem ugruntowanych technologii (WET - szwy, zszywki, wypełnienia dentystyczne, aparaty dentystyczne, korony zębów, śruby, kliny, płytki, druty, szpilki, klipsy i łączniki),
- b) 31 grudnia 2028 r., dla wyrobów klasy IIb innych niż objęte lit. a) powyżej, dla wyrobów klasy IIa oraz dla wyrobów klasy I wprowadzanych do obrotu w stanie sterylnym (Is) lub posiadających funkcję pomiarową (Im),
- c) 31 grudnia 2028 r. dla wyrobów, dla których procedura oceny zgodności zgodnie z MOD nie wymagała zaangażowania jednostki notyfikowanej, ale dla których procedura oceny zgodności zgodnie z MDR wymaga zaangażowania jednostki notyfikowanej, np. wyroby klasy I kwalifikujące się jako narzędzia chirurgiczne wielokrotnego użytku (Ir)

Z poważaniem

IMQ S.p.A.
Kierownik Działu
Wyrobow Medycznych

(B. Venturelli)

(podpis nieczytelny)

(w stopce dane biznesowe i bankowe firmy IMQ S.p.A.)

Tabela 1: Wyroby objęte niniejszym pismem, w przypadku których **IMQ S.p.A.** jest również odpowiedzialna za właściwy nadzór nad odpowiednimi wyrobami zgodnie z (AI)MDD

Wyrób (nazwa lub podstawowy kod UDI-DI) zgodnie ze zgłoszenia MDR	Klasyfikacja - wyrobu zgodnie ze zgłoszeniem MDR (1)	Jeśli wyrób objęty zgłoszeniem MDR jest wyrobem zastępczym, identyfikacja odpowiedniego wyrobu (AI)MDD	Odniesienie do odpowiedniego certyfikatu (AI)MDD i numer identyfikacyjny jednostki notyfikowanej
WYKAZ WYROBÓW W ZAŁĄCZNIKACH			

(1) Klasyfikacja wyrobu w ramach zgłoszenia MDR, zaproponowana przez producenta zgodnie z załącznikiem VIII do MDR i wstępnie zweryfikowana przez jednostkę notyfikowaną zgodnie z sekcją 4.2 (d) załącznika VII do MDR

Tabela 2: Wyroby objęte niniejszym pismem, w przypadku których **IMQ S.p.A.** nie ponosi odpowiedzialności za właściwy nadzór nad odpowiednimi wyrobami zgodnie z (AI)MDD

Wyrób (nazwa lub podstawowy kod UDI-DI) zgodnie ze zgłoszenia MDR	Klasyfikacja - wyrobu zgodnie ze zgłoszeniem MDR (1)	Jeśli wyrób objęty zgłoszeniem MDR jest wyrobem zastępczym, identyfikacja odpowiedniego wyrobu (AI)MDD	Odniesienie do odpowiedniego certyfikatu (AI)MDD i numer identyfikacyjny jednostki notyfikowanej
n/d	n/d	n/d	n/d

Tabela 3: Historia zmian niniejszego pisma potwierdzającego

Data	Nr protokołu	Działanie
2024/05/17	FP-2988/24-nc10	Wydanie pierwsze
2024/06/01	FP-3366/24-nc10	Korekta i dodawanie urządzeń VR16120-20 i VR16150-20 do tabeli 2
2024/09/26	FP-5637/24-fg10	Tabela 1/ Przenoszenie urządzeń z Tabeli 2 do Tabeli 1. W załączeniu nr „REF.” wymienione są w „Szczegółowej liście numerów referencyjnych MDD” z 2024/09/23, zgodnie z Umową o przeniesieniu.