



YUKON MEDICAL, LLC • 4021 Stirrup Creek Drive, Suite 200 • Durham, NC 27703  
919.595.8250 • 919.595.8251 Fax • [www.yukonmedical.com](http://www.yukonmedical.com)

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Yukon Medical, LLC  
4021 Stirrup Creek Drive  
Suite 200  
Durham, NC 27703

July 18, 2023

### **YUKON MEDICAL SELF DECLARATION**

To Our Valued Customers:

With regards to the MDR 2017/745 Transition Extension, this declaration confirms that Yukon Medical, LLC has completed a formal application in accordance with Section 4.3, first subparagraph of Annex VII of EU 2017/745 MDR and has signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII of 2017/745 MDR with the following Notified Body:

BSI Group  
The Netherlands B.V.  
Say Building  
John M. Keynesplein 9, 1066 EP  
Amsterdam, The Netherlands  
ID Number: NB 2797

These activities have been confirmed in the Notified Body Confirmation Letter Reference EU2023-607/646105 issued on June 21, 2023, by BSI Group. A copy of the letter is included with this declaration (Attachment 1).

The devices covered by the formal application and the written agreement mentioned above were originally CE Marked under MDD 93/42/EEC and stated in certificate CE 597920. The devices are safe, do not represent an unacceptable risk to users, patients or public health and have not undergone any significant changes to the design or intended purpose. Table 1 identifies the devices for which an MDR application has been received, written agreement concluded and for which the NB is also responsible for and agreed to appropriate surveillance of the corresponding devices under the applicable Directive.



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**Table 1: Devices covered by this letter and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive:**

<b>Device name or Basic UDI-DI (under MDR application)</b>	<b>Part Number</b>	<b>MDR Device classification (as proposed by the manufacturer &amp; verified at the pre-application stage)</b>	<b>If the MDR device is a substitute device, ID of the corresponding MDD/AIMDD device</b>
Closed Male Luer	YM007, YM058	Class IIa	N/A
Neutral Valve	YM004	Class IIa	N/A
Non-Vented Vial Access Device	YM000, YM001, YM002, YM003 MV0613-0006, MV0620-0006	Class I device placed on the market in sterile condition	N/A
Vented Single Vial Access Device	YM005, YM011, YM012, YM020, ADA-010	Class I device placed on the market in sterile condition	N/A
Universal SVAD with SmartSite®	MV0400-0006, MV040010-0006, MV040025-0006	Class I device placed on the market in sterile condition	N/A
Vented Vial Access Device with SmartSite®	MV0413-0006, MV0420-0006, MV0428-0006, MV042005-0006, MV042025-0006	Class I device placed on the market in sterile condition	N/A
Closed Vial Access Device with SmartSite®	MV0513-0006, MV0520-0006, MV0528-0006, MV0550-0006	Class I device placed on the market in sterile condition	N/A
Multi-Dose Vented Vial Spike and Vialok® MV	YM035, YM036, YM038, YM039	Class I device placed on the market in sterile condition	N/A
Arisure® Dry Spike	YM050, YM064	Class IIa	N/A
Arisure® Closed Vial Adapters	YM051, YM053, YM054	Class IIa	N/A
Spike Adapter with CML	YM060	Class IIa	N/A
Vented Bag Spike	YM062	Class IIa	N/A
Vialok® MN	YM033, YM034	Class I device placed on the market in sterile condition	N/A
ClearTip Swab™ Contoured (Mid-Turbinate Swab)	YM202, YM205	Class I device placed on the market in sterile condition	N/A
ClearTip Swab™ Contoured Mini (Nasal Swab)	YM201, YM203	Class I device placed on the market in sterile condition	N/A
Bag Spike	YM061	Class IIa	N/A



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The transition timeline that applies to the devices covered by this declaration, subject to the conditions specified in Article 120.3c of MDR (as amended by (EU) 2023/607), is shown below:

- 31 December 2028 for other Class IIb devices, Class IIa, Class I devices placed on the market in sterile condition or have a measuring function.

Copies of a Free Sale Certificate for the products listed in Table 1 will be made available upon request if and when one is provided by Yukon's Notified Body.

On behalf of Yukon Medical, LLC

A handwritten signature in black ink, appearing to read "Pamela McNulty", is written over a light blue horizontal line.

Pamela McNulty

Sr. Dir. QA and Compliance

Attachment 1: Notified Body Confirmation Letter, Reference: EU2023-607/646105