

MANUFACTURER'S DECLARATION

in relation to Regulation (EU) 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices, in particular with respect to

- the validity of certificates issued under Council Directive 90/385/EEC on Active Implantable Medical Devices (AIMDD) or Council Directive 93/42/EEC on Medical Devices (MDD) (Directive Certificates) *and/or*¹
- the compliance of the devices and us as their manufacturer with the conditions for the continued placing on the market and putting into service

| | |
|---|---|
| Manufacturer name | B. Braun Melsungen AG |
| Manufacturer address and contact details | Carl-Braun Straße 1 34212 Melsungen GERMANY |
| Single Registration Number (SRN) (if available) | DE-MF-000000201 |

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|---|-----|
| Authorised Representative name (if applicable) | N/A |
| Authorised Representative address and contact details | N/A |
| Single Registration Number (SRN) (if available) | N/A |

¹ The first condition is not applicable in case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body.

| | | |
|---|---|---|
| Notified body name (if applicable) | TÜV SÜD Product Service GmbH | <input checked="" type="checkbox"/> See attached schedule |
| Notified body number (if applicable) | 0123 | <input checked="" type="checkbox"/> See attached schedule |
| Directive Certificate number(s) to which this confirmation is made (if applicable) | (1) G1 012974 0607; (2) G7 012974 0612; (3) G7 012974 0593; (4) G7 012974 0592; | <input checked="" type="checkbox"/> See attached schedule |
| Original expiry date as indicated on the Directive Certificate prior to the extension of the validity (if applicable) | (1) 2024-05-26; (2) 2024-05-26; (3) 2024-05-26; (4) 2024-05-26 | <input checked="" type="checkbox"/> See attached schedule |
| End date of extended validity/transition period | 2027-12-31 | <input checked="" type="checkbox"/> See attached schedule |

We, as the manufacturer declare under our sole responsibility:

- for the above listed **Directive Certificate** (or see attached schedule, if multiple certificates) the conditions for the legal extension of validity as required in Article 120.2 of the MDR are met *and/or*²
- the listed **device(s)** in the attached schedule and we as their manufacturer are in compliance with the conditions listed in Article 120.3c of the MDR for continued placing on the market and putting into service,

namely by fulfilling the following conditions:

- **Directive Certificate(s)** as listed above or in the attached schedule
 - Directive Certificate(s) covering the listed device(s) was/were issued after 25 May 2017, was/were valid on 26 May 2021 and have not been withdrawn afterwards.

Choose applicable statements:

- ☐ Expired *before* 20 March 2023:
- ☐ Before the original date of expiry as indicated on the Directive Certificate(s), we and the notified body have signed written agreement(s) in accordance with Section 4.3, second

² The first condition is not applicable in case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body

subparagraph of Annex VII to this Regulation for the conformity assessment(s) in respect of the device(s) covered by the expired certificate(s) or in respect of a device(s) intended to substitute that/those device(s), or

- ☐ A Competent Authority has granted a derogation from the applicable conformity assessment procedure in accordance with Article 59(1) MDR (may be provided upon request), or
- ☐ A Competent Authority has required the manufacturer, in accordance with Article 97(1) MDR, to carry out the applicable conformity assessment procedure (may be provided upon request)

Choose one of the following statements only if a derogation per Article 59(1) or a requirement per Article 97(1) has been granted by a Competent Authority:

- ☐ Formal application(s) to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has/have been made or will be made/submitted by us to a notified body no later than 26 May 2024 for the device(s) listed in the attached schedule or its/their substitute(s) and signed written agreement(s) is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.
- ☐ We do not intent to lodge an application for conformity assessment by 26 May 2024, therefore the transition period will end on 26 May 2024.

- ☒ Expired/expires *after* 20 March 2023:

Choose one applicable statement:

- ☒ Formal application(s) to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has/have been made or will be made/submitted by us to a notified body no later than 26 May 2024 for the device(s) listed in the attached schedule or its/their substitute(s) and signed written agreement(s) is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.
- ☐ We do not intent to lodge an application for conformity assessment by 26 May 2024, therefore the transition period will end on 26 May 2024.

➤ Upclassified devices

In case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body:

Choose one applicable statement:

- ☐ Formal application(s) to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has/have been made or will be made/submitted by us to a notified body no later than 26 May 2024 for the device(s) listed in the attached schedule or its/their substitutes and signed written agreement(s) is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.
- ☐ We do not intent to lodge an application for conformity assessment by 26 May 2024, therefore the transition period will end on 26 May 2024.

➤ Quality Management System (QMS)

Choose one applicable statement:

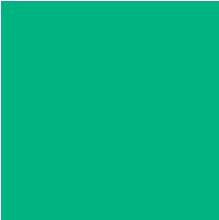
- ☐ A QMS in accordance with Article 10(9) MDR will be put in place by no later than 26 May 2024.
- ☐ A QMS in accordance with Article 10(9) MDR is in place.
- ☒ A notified body has issued the attached certificate for the MDR-compliant QMS.

➤ Device(s) as listed in the attached schedule

- The device(s) continue to comply with the AIMDD or MDD.
- There are no significant changes in the design and intended purpose.
- The device(s) do not present an unacceptable risk to health or safety of patients, users or other persons, or to other aspects of the protection of public health.

Signed for and on behalf of the manufacturer:

| | Quality Management | Regulatory Affairs |
|-------------------|---|--|
| Full Company Name | B. Braun Melsungen AG | B. Braun Melsungen AG |
| Location & Date | Melsungen, 2024-04-15 | Melsungen, 2024-04-15 |
| Signature | See electronic signature | See electronic signature |
| Print Name | (1) Thomas Brand; (2) Dr. Frank Ritz | (3) Dr. Stefan Seidel; (4) Dr. Joachim Buenger |
| Title | (1) Vice President Quality Management for non-active Medical Devices; (2) Vice | (3) Head of Regulatory Affairs CoE Infusion & Pain Therapy; (4) Director Template & Submission Mgmt |



| | | |
|----------------------------------|--|---------------------|
| | President QM Pharma; Hospital Care Division | |
| Contact Details (at least email) | BBMAG-HC@bbraun.com | BBMAG-HC@bbraun.com |
| Version of document | Version 1.0 | |

B. Braun Melsungen AG - Document No.: G12 - Version: 1.0 - Document ID: RE-QM-DIV-000445 - Effective Date: 2024-05-06
Title: BBMAG_LM_confirmation letter_Regulation EU 2023/607_G12

Schedule of Devices

The above Manufacturer's Declaration is valid for the following devices:

Effective

| Identification of the device(s) ³ (e.g., device name, family/group name device model or catalogue number) | | Directive Certificate number(s) to which this confirmation is made (if applicable) | Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity (if applicable) | Notified Body name and number that issued the Directive Certificate (if applicable) | Notified Body name and number where the MDR application was lodged/contract signed (if applicable) | End date of extended validity / transition period | Substitute Device(s) (if applicable) |
|---|---|--|---|---|---|---|---|
| Article name | Article Number (under MDR application) | Basic UDI-DI (under MDR application) | | | | | |
| Perifix® Catheter | 4513150 | 403923900000023832S | | | | | |
| Perifix® Catheter | 4513258 | G1 012974 0607; G7 012974 0612; NB0123 | | | | | |
| Perifix® Catheter | 4513177 | | | | | | |
| Perifix® Soft Tip Catheter | 4515048 | | | | | | |
| Perifix® Catheter NRFit® | 4513258N-01 | | | | | | |
| Perifix® Catheter NRFit® | 4513150N-01 | | | | | | |
| Perifix® Catheter NRFit® | 4513177N-01 | | | | | | |
| | | | | | | | N/A |
| | | | | | | | Effect |

Effective

³ for devices with AIMDD/MDD certificate(s) the identification should be as in the certificate, and only if the certificate has a generic scope it should be as defined above)

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|---|--|--|---|---|--|---|--------------------------------------|
| Article name | Article Number (under MDR application) | Basic UDI-DI (under MDR application) | | | | | |
| Perifix® SoftTip Catheter NRFit® | 4515048N-01 | | | | | | |
| Perifix® ONE Catheter | 4513150C | | | | | | |
| Perifix® ONE Catheter | 4513258C | | | | | | |
| Perifix® ONE Catheter NRFit® | 45132581N-01 | | | | | | |
| Perifix® ONE Catheter NRFit® | 45131501N-01 | | | | | | |
| Perifix® ONE Catheter NRFit® | 45131501N-01 | | | | | | |

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| Article name | Article Number (under MDR application) | Basic UDI-DI (under MDR application) | | | | | |
| Perifix 400 | 4514009 | 40392390000023842U | | | | | |
| Perifix 401 | 4514017 | G1 012974 0607; G7 012974 0612; NB0123 | | | | | |
| Perifix 402 | 4514025 | | | | | | |
| Perifix 451 | 4514513 | | | | | | |
| Perifix Soft Tip 701 | 4510097 | | | | | | |
| Perifix Soft Tip 700 | 4510216 | | | | | | |
| Perifix Soft Tip 730 | 4517309 | | | | | | |
| Perifix Soft Tip 750 | 4517504 | | | | | | |
| Perifix 100 | 4511000 | | | | | | |
| Perifix 300 | 4513002 | TÜV SÜD Product Service GmbH (NB0123) TÜV SÜD Product Service GmbH (NB0123) | | | | | |
| Perifix 301 | 4513010 | | | | | | |
| | | 2024-05-26 | | TÜV SÜD Product Service GmbH (NB0123) | | 2027-12-31 | N/A |
| | | 2024-05-26 | | TÜV SÜD Product Service GmbH (NB0123) | | 2027-12-31 | |

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|---|--|--|---|---|--|---|--------------------------------------|
| Article name | Article Number (under MDR application) | Basic UDI-DI (under MDR application) | | | | | |
| Perifix 302 | 4513029 | | | | | | |
| Perifix 310 | 4513100 | | | | | | |
| Perifix 400 NRFit | 4514009N-01 | | | | | | |
| Perifix 401 NRFit | 4514017N-01 | | | | | | |
| Perifix 402 NRFit | 4514025N-01 | | | | | | |
| Perifix Soft Tip 701 NRFit | 4510097N-01 | | | | | | |
| Perifix Soft Tip 730 NRFit | 4517309N-01 | | | | | | |
| Perifix 300 NRFit | 4513002N-01 | | | | | | |
| Perifix ONE 400 | 4514009C | | | | | | |
| Perifix ONE 401 | 4514017C | | | | | | |

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| Article name | Article Number (under MDR application) | Basic UDI-DI (under MDR application) | | | | | |
| Perifix ONE 402 | 4514025C | | | | | | |
| Perifix ONE 418 | 4514183C | | | | | | |
| Perifix ONE 451 | 4514513C | | | | | | |
| Perifix ONE 401 NRFit | 45140171N-01 | | | | | | |
| Perifix ONE 402 NRFit | 45140251N-01 | | | | | | |
| Perifix 420 | 4514203 | | | | | | |
| Perifix 421 | 4514211 | | | | | | |
| Perifix 430 | 4514300 | | | | | | |
| Perifix 431 | 4514319 | | | | | | |
| Perifix 620 | 4516206 | | | | | | |
| Perifix Soft Tip 900 | 4510291 | | | | | | |
| Perifix Soft Tip 901 | 4510305 | | | | | | |
| Perifix 421 NRFit | 4514211N-01 | | | | | | |

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|---|---|--|---|---|---|---|---|
| Article name | Article Number (under MDR application) | Basic UDI-DI (under MDR application) | | | | | |
| Perifix Soft Tip 901 NRFit | 4510305N-01 | | | | | | |
| Perifix ONE 420 | 4514203C | | | | | | |
| Perifix ONE 421 | 4514211C | | | | | | |
| Perifix ONE 431 | 4514319C | | | | | | |
| Perifix ONE Paed Set 18 | 4512006C | | | | | | |
| Perifix ONE Paed Set 20 | 4512014C | | | | | | |
| Perifix ONE 421 NRFit | 4514211N- 01 | | | | | | |
| Perifix ONE Paed Set 18 NRFit | 45120061N- 01 | | | | | | |
| Perifix ONE Paed Set 20 NRFit | 45120141N- 01 | | | | | | |

Effective

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Effective

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|---|--|--|---|---|--|---|--------------------------------------|
| Article name | Article Number (under MDR application) | Basic UDI-DI (under MDR application) | | | | | |
| Espocan | 4556674 | 40392390000023862Y | | | | | |
| Espocan | 4556666 | G1 012974 0607; | | | | | |
| Espocan with Docking System | 4556747 | G7 012974 0612; NB0123 | | | | | |
| Espocan with Docking System | 4556763 | | | | | | |
| Espocan NRFit | 4556674N-01 | | | | | | |
| Espocan NRFit | 4556666N-01 | | | | | | |
| | | | | | | | N/A |

Effective

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|---|---|--|---|---|---|---|---|
| Article name | Article Number (under MDR application) | | | | | | |
| Espocan NRFit with Docking System | 4556747N-01 | | | | | | |
| Espocan NRFit with Docking System | 4556763N-01 | | | | | | |
| Certofix® Mono Paed S 4160177 110 | | G1 012974 0607; G7 012974 0593; NB0123 | 2024-05-26 2024-05-26 | TÜV SÜD Product Service GmbH (NB0123) TÜV SÜD Product Service GmbH (NB0123) | TÜV SÜD Product Service GmbH (NB0123) TÜV SÜD Product Service GmbH (NB0123) | 2027-12-31 2027-12-31 | N/A |
| | 40392390000007422J | | | | | | |
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|---|--|--|---|---|--|---|--------------------------------------|
| Article name | Article Number (under MDR application) | Basic UDI-DI (under MDR application) | | | | | |
| Certofix® Mono S 215 | 4160185-07 | | | | | | |
| Certofix® Mono 215 | 4160185E | | | | | | |
| Certofix® Mono 215 | 4160185E-07 | | | | | | |
| Certofix® Mono S 220 | 4160207 | | | | | | |
| Certofix® Mono S 220 | 4160207-07 | | | | | | |
| Certofix® Mono 220 | 4160207E | | | | | | |
| Certofix® Mono 220 | 4160207E-07 | | | | | | |
| Certofix® Mono 220 R | 4160207R | | | | | | |
| Certofix® Mono V 220 | 4160215 | | | | | | |
| Certofix® Mono V 220 | 4160215-07 | | | | | | |

Effective

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³ for devices with AIMDD/MDD certificate(s) the identification should be as in the certificate, and only if the certificate has a generic scope it should be as defined above)



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|---|---|--|---|---|---|---|---|
| Article name | Article Number (under MDR application) | Basic UDI-DI (under MDR application) | | | | | |
| Certofix [®] Mono S 315 | 4160223 | | | | | | |
| Certofix [®] Mono S 315 | 4160223-07 | | | | | | |
| Certofix [®] Mono 315 | 4160223E | | | | | | |
| Certofix [®] Mono 315 | 4160223E-07 | | | | | | |
| Certofix [®] Mono V 315 | 4160231 | | | | | | |
| Certofix [®] Mono V 315 | 4160231-07 | | | | | | |
| Certofix [®] Mono S 320 | 4160258 | | | | | | |
| Certofix [®] Mono S 320 | 4160258-07 | | | | | | |
| Certofix [®] Mono 320 | 4160258E | | | | | | |
| Certofix [®] Mono 320 | 4160258E-07 | | | | | | |

Effective

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|---|---|--|---|---|---|---|---|
| Article name | Article Number (under MDR application) | Basic UDI-DI (under MDR application) | | | | | |
| Certofix® Mono 320 R | 4160258R | | | | | | |
| Certofix® Safety Mono S 320 | 4160258S | | | | | | |
| Certofix® Safety Mono S 320 | 4160258S-07 | | | | | | |
| Certofix® Mono V 320 | 4160266 | | | | | | |
| Certofix® Mono V 320 | 4160266-07 | | | | | | |
| Certofix® Mono S 330" | 4160282 | | | | | | |
| Certofix® Mono S 330 | 4160282-07 | | | | | | |
| Certofix® Mono 330 | 4160282E | | | | | | |
| Certofix® Mono 330" | 4160282E-07 | | | | | | |

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|---|---|--|---|---|---|---|---|
| Article name | Article Number (under MDR application) | Basic UDI-DI (under MDR application) | | | | | |
| Certofix [®] Safety Mono S 330 | 4160282S | | | | | | |
| Certofix [®] Safety Mono S 330 | 4160282S-07 | | | | | | |
| Certofix [®] Mono V 330 | 4160290 | | | | | | |
| Certofix [®] Mono V 330 | 4160290-07 | | | | | | |
| Certofix [®] Mono S 420" | 4160304 | | | | | | |
| Certofix [®] Mono S 420" | 4160304-07 | | | | | | |
| Certofix [®] Mono 420 | 4160304E | | | | | | |
| Certofix [®] Mono 420 | 4160304E-07 | | | | | | |

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|---|--|--|---|---|--|---|--------------------------------------|
| Article name | Article Number (under MDR application) | Basic UDI-DI (under MDR application) | | | | | |
| Certofix® Mono 420 R | 4160304R | | | | | | |
| Certofix® Mono V 420 | 4160320 | | | | | | |
| Certofix® Mono V 420 | 4160320-07 | | | | | | |
| Certofix® Mono S 415 | 4160509 | | | | | | |
| Certofix® Mono S 415 | 4160509-07 | | | | | | |
| Certofix® Mono 415 | 4160509E | | | | | | |
| Certofix® Mono 415 | 4160509E-07 | | | | | | |
| Certofix® Mono V 415 | 4160517 | | | | | | |
| Certofix® Mono V 415 | 4160517-07 | | | | | | |
| Certofix® Trio HF S 1215 | 4160578 | | | | | | |

Effective

³ for devices with AIMDD/MDD certificate(s) the identification should be as in the certificate, and only if the certificate has a generic scope it should be as defined above)

Schedule of Devices

The above Manufacturer's Declaration is valid for the following devices:

Effective

| Identification of the device(s) ³ (e.g., device name, family/group name device model or catalogue number) | | Directive Certificate number(s) to which this confirmation is made (if applicable) | Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity (if applicable) | Notified Body name and number that issued the Directive Certificate (if applicable) | Notified Body name and number where the MDR application was lodged/contract signed (if applicable) | End date of extended validity / transition period | Substitute Device(s) (if applicable) |
|---|--|--|---|---|--|---|--------------------------------------|
| Article name | Article Number (under MDR application) | Basic UDI-DI (under MDR application) | | | | | |
| Certofix® Trio HF S 1215 | 4160578-07 | | | | | | |
| Certofix® Trio HF S 1220 | 4160586 | | | | | | |
| Certofix® Trio HF S 1220 | 4160586-07 | | | | | | |
| Certofix® Trio HF V 1215 | 4160614 | | | | | | |
| Certofix® Trio HF V 1215 | 4160614-07 | | | | | | |
| Certofix® Trio HF V 1220 | 4160622 | | | | | | |
| Certofix® Trio HF V 1220 | 4160622-07 | | | | | | |

Effective

³ for devices with AIMDD/MDD certificate(s) the identification should be as in the certificate, and only if the certificate has a generic scope it should be as defined above)

Schedule of Devices

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|---|--|--|---|---|--|---|--------------------------------------|
| Article name | Article Number (under MDR application) | Basic UDI-DI (under MDR application) | | | | | |
| Certofix® Mono S 430 | 4160762 | | | | | | |
| Certofix® Mono S 430 | 4160762-07 | | | | | | |
| Certofix® Mono 430 | 4160762E | | | | | | |
| Certofix® Mono 430 | 4160762E-07 | | | | | | |
| Certofix® Mono V 430 | 4160789 | | | | | | |
| Certofix® Mono V 430 | 4160789-07 | | | | | | |
| Certofix® Trio 715 | 4161157E | | | | | | |
| Certofix® Trio 715 | 4161157E-07 | | | | | | |
| Certofix® Trio S 715 | 4161159 | | | | | | |
| Certofix® Trio S 715 | 4161159-07 | | | | | | |

Effective

³ for devices with AIMDD/MDD certificate(s) the identification should be as in the certificate, and only if the certificate has a generic scope it should be as defined above)

Schedule of Devices

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|---|--|--|---|---|--|---|--------------------------------------|
| Article name | Article Number (under MDR application) | Basic UDI-DI (under MDR application) | | | | | |
| Certofix® Duo V 720 | 4161211 | | | | | | |
| Certofix® Duo V 720 | 4161211-07 | | | | | | |
| Certofix® Duo V 730 | 4161319 | | | | | | |
| Certofix® Duo V 730 | 4161319-07 | | | | | | |
| Certofix® Trio V 715 | 4162153 | | | | | | |
| Certofix® Trio V 715 | 4162153-07 | | | | | | |
| Certofix® Duo 720 | 4162200E | | | | | | |
| Certofix® Duo 720 | 4162200E-07 | | | | | | |
| Certofix® Duo 730 | 4162307E | | | | | | |
| Certofix® Duo 730 | 4162307E-07 | | | | | | |

Effective

³ for devices with AIMDD/MDD certificate(s) the identification should be as in the certificate, and only if the certificate has a generic scope it should be as defined above)



Schedule of Devices

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|---|---|--|---|---|---|---|---|
| Article name | Article Number (under MDR application) | Basic UDI-DI (under MDR application) | | | | | |
| Certofix® Trio 720 | 4163206E | | | | | | |
| Certofix® Trio 720 | 4163206E-07 | | | | | | |
| Certofix® Trio V 720 | 4163214 | | | | | | |
| Certofix® Trio V 720 | 4163214-07 | | | | | | |
| Certofix® Trio 730 | 4163303E | | | | | | |
| Certofix® Trio 730 | 4163303E-07 | | | | | | |
| Certofix® Trio S 730 | 4163306 | | | | | | |
| Certofix® Trio S 730 | 4163306-07 | | | | | | |
| Certofix® Safety Trio S 730 | 4163306S | | | | | | |

³ for devices with AIMDD/MDD certificate(s) the identification should be as in the certificate, and only if the certificate has a generic scope it should be as defined above)

Schedule of Devices

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|---|---|--|---|---|---|---|---|
| Article name | Article Number (under MDR application) | Basic UDI-DI (under MDR application) | | | | | |
| Certofix [®] Safety Trio S 730 | 4163306S-07 | | | | | | |
| Certofix [®] Trio V 730 | 4163311 | | | | | | |
| Certofix [®] Trio V 730 | 4163311-07 | | | | | | |
| Certofix [®] Duo 715 | 4164156E | | | | | | |
| Certofix [®] Duo 715 | 4164156E-07 | | | | | | |
| Certofix [®] Duo S 715 | 4164158 | | | | | | |
| Certofix [®] Duo S 715 | 4164158-07 | | | | | | |
| Certofix [®] Duo V 715 | 4166159 | | | | | | |
| Certofix [®] Duo V 715 | 4166159-07 | | | | | | |

Effective

Approval confirms: Correct document attached / complete document attached / scan is readable
Freigabe bestätigt: Dokument Richtig zugeordnet / vollständig und lesbar
Print Date - Gedruckt am: 2024-05-17 15:02 (CET)

³ for devices with AIMDD/MDD certificate(s) the identification should be as in the certificate, and only if the certificate has a generic scope it should be as defined above)

Schedule of Devices

The above Manufacturer's Declaration is valid for the following devices:

Effective

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|---|--|--|---|---|--|---|--------------------------------------|
| Article name | Article Number (under MDR application) | Basic UDI-DI (under MDR application) | | | | | |
| Certofix® Quinto V 1215 | 4166841 | | | | | | |
| Certofix® Quinto V 1215 | 4166841-07 | | | | | | |
| Certofix® Quinto S 1220 | 4166852 | | | | | | |
| Certofix® Quinto S 1220 | 4166852-07 | | | | | | |
| Certofix® Safety Quinto S 1220 | 4166852S | | | | | | |
| Certofix® Safety Quinto S 1220 | 4166852S-07 | | | | | | |

Effective

³ for devices with AIMDD/MDD certificate(s) the identification should be as in the certificate, and only if the certificate has a generic scope it should be as defined above)

Schedule of Devices

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Effective

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|---|---|--|---|---|---|---|---|
| Article name | Article Number (under MDR application) | Basic UDI-DI (under MDR application) | | | | | |
| Certofix® Quinto V 1220 | 4166868 | | | | | | |
| Certofix® Quinto V 1220 | 4166868-07 | | | | | | |
| Certofix® Duo Paed S 408 | 4166906 | | | | | | |
| Certofix® Duo Paed S 408 | 4166906-07 | | | | | | |
| Certofix® Duo Paed S 413 | 4166922 | | | | | | |
| Certofix® Duo Paed S 413 | 4166922-07 | | | | | | |
| Certofix® Duo Paed S 420 | 4166949 | | | | | | |

Effective

³ for devices with AIMDD/MDD certificate(s) the identification should be as in the certificate, and only if the certificate has a generic scope it should be as defined above)

Schedule of Devices

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|---|---|--|---|---|---|---|---|
| Article name | Article Number (under MDR application) | Basic UDI-DI (under MDR application) | | | | | |
| Certofix® Duo Paed S 420 | 4166949-07 | | | | | | |
| Certofix® Duo Paed S 508 | 4167112 | | | | | | |
| Certofix® Duo Paed S 508 | 4167112-07 | | | | | | |
| Certofix® Duo Paed S 513 | 4167139 | | | | | | |
| Certofix® Duo Paed S 513 | 4167139-07 | | | | | | |
| Certofix® Duo Paed S 520 | 4167155 | | | | | | |
| Certofix® Duo Paed S 520 | 4167155-07 | | | | | | |

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Freigabe bestätigt: Dokument Richtig zugeordnet / vollständig und lesbar
Print Date - Gedruckt am: 2024-05-17 15:02 (CET)

³ for devices with AIMDD/MDD certificate(s) the identification should be as in the certificate, and only if the certificate has a generic scope it should be as defined above)

Schedule of Devices

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|---|--|--|---|---|--|---|--------------------------------------|
| Article name | Article Number (under MDR application) | Basic UDI-DI (under MDR application) | | | | | |
| Certofix® Trio Paed S 508 | 4167228 | | | | | | |
| Certofix® Trio Paed S 508 | 4167228-07 | | | | | | |
| Certofix® Trio Paed S 513 | 4167244 | | | | | | |
| Certofix® Trio Paed S 513 | 4167244-07 | | | | | | |
| Certofix® Trio Paed S 520 | 4167260 | | | | | | |
| Certofix® Trio Paed S 520 | 4167260-07 | | | | | | |
| Certofix® Duo S 720 | 4167385 | | | | | | |

Effective

³ for devices with AIMDD/MDD certificate(s) the identification should be as in the certificate, and only if the certificate has a generic scope it should be as defined above)

Effective

Schedule of Devices

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Effective

| Identification of the device(s) ³ (e.g., device name, family/group name device model or catalogue number) | | Directive Certificate number(s) to which this confirmation is made (if applicable) | Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity (if applicable) | Notified Body name and number that issued the Directive Certificate (if applicable) | Notified Body name and number where the MDR application was lodged/contract signed (if applicable) | End date of extended validity / transition period | Substitute Device(s) (if applicable) |
|---|--|--|---|---|--|---|--------------------------------------|
| Article name | Article Number (under MDR application) | Basic UDI-DI (under MDR application) | | | | | |
| Certofix® Duo S 720 | 4167385-07 | | | | | | |
| Certofix® Safety Duo S 720 | 4167385S | | | | | | |
| Certofix® Safety Duo S 720 | 4167385S-07 | | | | | | |
| Certofix® Duo S 730 | 4167394 | | | | | | |
| Certofix® Duo S 730 | 4167394-07 | | | | | | |
| Certofix® Safety Duo S 730 | 4167394S | | | | | | |
| Certofix® Safety Duo S 730 | 4167394S-07 | | | | | | |
| Certofix® Trio S 720 | 4167408 | | | | | | |

Effective

³ for devices with AIMDD/MDD certificate(s) the identification should be as in the certificate, and only if the certificate has a generic scope it should be as defined above)

Schedule of Devices

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Effective

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|---|--|--|---|---|--|---|--------------------------------------|
| Article name | Article Number (under MDR application) | Basic UDI-DI (under MDR application) | | | | | |
| Certofix® Trio S 720 | 4167408-07 | | | | | | |
| Certofix® Safety Trio S 720 | 4167408S | | | | | | |
| Certofix® Safety Trio S 720 | 4167408S-07 | | | | | | |
| Certofix® Duo HF V 920 | 4167511 | | | | | | |
| Certofix® Duo HF V 920 | 4167511-07 | | | | | | |
| Certofix® Duo HF V 1215 | 4167538 | | | | | | |
| Certofix® Duo HF V 1215 | 4167538-07 | | | | | | |

Effective

³ for devices with AIMDD/MDD certificate(s) the identification should be as in the certificate, and only if the certificate has a generic scope it should be as defined above)

Schedule of Devices

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|---|--|--|---|---|--|---|--------------------------------------|
| Article name | Article Number (under MDR application) | Basic UDI-DI (under MDR application) | | | | | |
| Certofix® Duo HF V 1220 | 4167546 | | | | | | |
| Certofix® Duo HF V 1220 | 4167546-07 | | | | | | |
| Certofix® Quattro V 815 | 4167767 | | | | | | |
| Certofix® Quattro V 815 | 4167767-07 | | | | | | |
| Certofix® Quattro V 820 | 4167775 | | | | | | |
| Certofix® Quattro V 820 | 4167775-07 | | | | | | |

Effective

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Schedule of Devices

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|---|--|--|---|---|--|---|--------------------------------------|
| Article name | Article Number (under MDR application) | Basic UDI-DI (under MDR application) | | | | | |
| Certofix® Safety Quattro V 820 | 4167775S | | | | | | |
| Certofix® Safety Quattro V 820 | 4167775S-07 | | | | | | |
| Certofix® Quattro V 830 | 4167783 | | | | | | |
| Certofix® Quattro V 830 | 4167783-07 | | | | | | |
| Certofix® Duo HF V 715 | 4168518 | | | | | | |
| Certofix® Duo HF V 715 | 4168518-07 | | | | | | |

Effective

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Schedule of Devices

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|---|--|--|---|---|--|---|--------------------------------------|
| Article name | Article Number (under MDR application) | Basic UDI-DI (under MDR application) | | | | | |
| Certofix® Duo HF S 720 | 4168528 | | | | | | |
| Certofix® Duo HF S 720 | 4168528-07 | | | | | | |
| Certofix® Duo HF V 720 | 4168534 | | | | | | |
| Certofix® Duo HF V 720 | 4168534-07 | | | | | | |
| Certofix® protect Mono V 320 | 4160266P | 40392390000025883E | | | | | |
| Certofix® protect Mono V 320 | 4160266P-07 | | | | | | |
| | | G1 012974 0607; | 2024-05-26 | TÜV SÜD Product Service GmbH (NB0123) | TÜV SÜD Product Service GmbH (NB0123) | 2027-12-31 | N/A |
| | | G7 012974 0593; NB0123 | 2024-05-26 | TÜV SÜD Product Service GmbH (NB0123) | TÜV SÜD Product Service GmbH (NB0123) | 2027-12-31 | |

Effective

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Print Date - Gedruckt am: 2024-05-17 15:02 (CET)

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|---|--|--|---|---|--|---|--------------------------------------|
| Article name | Article Number (under MDR application) | Basic UDI-DI (under MDR application) | | | | | |
| Certofix® protect Mono V 330 | 4160290P | | | | | | |
| Certofix® protect Mono V 330 | 4160290P-07 | | | | | | |
| Certofix® protect Mono V 420 | 4160320P | | | | | | |
| Certofix® protect Mono V 420 | 4160320P-07 | | | | | | |
| Certofix® protect Trio HF V 1220 | 4160622P | | | | | | |
| Certofix® protect Trio HF V 1220 | 4160622P-07 | | | | | | |
| Certofix® protect Mono V 430 | 4160789P | | | | | | |

Effective

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Schedule of Devices

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|---|--|--|---|---|--|---|--------------------------------------|
| Article name | Article Number (under MDR application) | Basic UDI-DI (under MDR application) | | | | | |
| Certofix® protect Mono V 430 | 4160789P-07 | | | | | | |
| Certofix® protect Duo V 720 | 4161211P | | | | | | |
| Certofix® protect Duo V 720 | 4161211P-07 | | | | | | |
| Certofix® protect Duo V 730 | 4161319P | | | | | | |
| Certofix® protect Duo V 730 | 4161319P-07 | | | | | | |
| Certofix® protect Trio V 715 | 4162153P | | | | | | |
| Certofix® protect Trio V 715 | 4162153P-07 | | | | | | |

Effective

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Schedule of Devices

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|---|--|--|---|---|--|---|--------------------------------------|
| Article name | Article Number (under MDR application) | Basic UDI-DI (under MDR application) | | | | | |
| Certofix® protect Trio V 720 | 4163214P | | | | | | |
| Certofix® protect Trio V 720 | 4163214P-07 | | | | | | |
| Certofix® protect Trio V 730 | 4163311P | | | | | | |
| Certofix® protect Trio V 730 | 4163311P-07 | | | | | | |
| Certofix® protect Duo V 715 | 4166159P | | | | | | |
| Certofix® protect Duo V 715 | 4166159P-07 | | | | | | |

Effective

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Schedule of Devices

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|---|--|--|---|---|--|---|--------------------------------------|
| Article name | Article Number (under MDR application) | Basic UDI-DI (under MDR application) | | | | | |
| Certofix® protect Quinto V 1220 | 4166868P | | | | | | |
| Certofix® protect Quinto V 1220 | 4166868P-07 | | | | | | |
| Certofix® protect Quattro V 815 | 4167767P | | | | | | |
| Certofix® protect Quattro V 815 | 4167767P-07 | | | | | | |
| Certofix® protect Quattro V 820 | 4167775P | | | | | | |

Effective

³ for devices with AIMDD/MDD certificate(s) the identification should be as in the certificate, and only if the certificate has a generic scope it should be as defined above)

Schedule of Devices

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|---|---|--|---|---|---|---|---|
| Article name | Article Number (under MDR application) | | | | | | |
| Certofix® protect Quattro V 820 | 4167775P-07 | Basic UDI-DI (under MDR application) | | | | | |
| Certofix® protect Quattro V 830 | 4167783P | | | | | | |
| Certofix® protect Quattro V 830 | 4167783P-07 | | | | | | |
| Certofix® protect Duo HF V 720 | 4168534P | | | | | | |
| Certofix® protect Duo HF V 720 | 4168534P-07 | | | | | | |
| | | | | | | | |

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| Spinocan® | 4521801 | 40392390000008612T | | | | | |
| | | G1 012974 0607; | 2024-05-26 | TÜV SÜD Product Service GmbH (NB0123) | TÜV SÜD Product Service GmbH (NB0123) | 2027-12-31 | 4501373 |
| Spinocan® | 4522001 | G7 012974 0592; NB0123 | 2024-05-26 | TÜV SÜD Product Service GmbH (NB0123) | TÜV SÜD Product Service GmbH (NB0123) | 2027-12-31 | 4501390 |
| Spinocan® | 4522201 | | | | | | 4509757 |
| Spinocan® | 4522202 | | | | | | 4509900 |
| Spinocan® | 4522203 | | | | | | 4507401 |
| Spinocan® | 4522204 | | | | | | 4507754 |
| Spinocan® | 4522501 | | | | | | 4507908 |
| Spinocan® | 4522502 | | | | | | 4506090 |
| Spinocan® | 4522503 | | | | | | 4505751 |
| Spinocan® | 4522502 | | | | | | 4505905 |
| Spinocan® | 4522601 | | | | | | 4505913 |
| Spinocan® | 4522701 | | | | | | 4502906 |
| Spinocan® | 4522702 | | | | | | 4504917 |
| | | | | | | | 4503902 |
| | | | | | | | 4502140 |

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³ for devices with AIMDD/MDD certificate(s) the identification should be as in the certificate, and only if the certificate has a generic scope it should be as defined above)

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| Article name | Article Number (under MDR application) | | | | | | |
| Spinocan® | 4522703 | | | | | | 4501900 |
| Spinocan® | 4522901 | | | | | | 4501918 |
| Pencan | 4532201 | | | | | | 4502035 |
| Pencan | 4532501 | | | | | | 4502167 |
| Pencan | 4532502 | | | | | | 4502159 |
| Pencan | 4532503 | | | | | | 4502019 |
| Pencan | 4532504 | | | | | | 4502043 |
| Pencan | 4532506 | | | | | | 4502116 |
| Pencan | 4532701 | | | | | | 4502175 |
| Pencan | 4532702 | | | | | | 4502027 |
| Pencan | 4532703 | | | | | | 4502051 |
| Pencan | 4532705 | | | | | | 4502124 |
| Pencan | 4532706 | | | | | | 4502132 |
| Atraucan® | 4542601 | | | | | | 4504771 |
| Atraucan® | 4542602 | | | | | | 4504763 |
| Atraucan® | 4542603 | | | | | | 4504739 |

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Effective

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| Article name | Article Number (under MDR application) | Basic UDI-DI (under MDR application) | | | | | |
| Spinocan® | 4521801N | | | | | | 4501390N-01 |
| Spinocan® | 4522001N | | | | | | 4501373N-01 |
| Spinocan® | 4522201N | | | | | | 4509757N-01 |
| Spinocan® | 4522202N | | | | | | 4509900N-01 |
| Spinocan® | 4522203N | | | | | | 4507401N-01 |
| Spinocan® | 4522204N | | | | | | 4507754N-01 |
| Spinocan® | 4522205N | | | | | | 4507908N-01 |
| Spinocan® | 4522206N | | | | | | 4506090N-01 |
| Spinocan® | 4522207N | | | | | | 4506095N-01 |
| Spinocan® | 4522208N | | | | | | 4505751N-01 |
| Spinocan® | 4522209N | | | | | | 4505905N-01 |

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| Article name | Article Number (under MDR application) | | | | | | |
| Spinocan® | 4522503N | | | | | | 4505913N-01 |
| | | | | | | | 4502906N-01 |
| Spinocan® | 4522601N | | | | | | 4504917N-01 |
| Spinocan® | 4522701N | | | | | | 4503902N-01 |
| Spinocan® | 4522702N | | | | | | 4502140N-01 |
| | | | | | | | 4501900N-01 |
| Spinocan® | 4522901N | | | | | | 4501901N-01 |
| | | | | | | | 4501918N-01 |
| Pencan | 4532201N | | | | | | 4502035N-01 |
| Pencan | 4532501N | | | | | | 4502167N-01 |
| Pencan | 4532502N | | | | | | 4502159N-01 |

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| Pencan | 4532503N | Basic UDI-DI (under MDR application) | | | | | 4502019N-01 |
| Pencan | 4532504N | | | | | | 4502043N-01 |
| Pencan | 4532506N | | | | | | 4502044N-01 |
| Pencan | 4532507N | | | | | | 4502116N-01 |
| Pencan | 4532510N | | | | | | 4502117N-01 |
| Pencan | 4532701N | | | | | | 4502120N-01 |
| Pencan | 4532702N | | | | | | 333877N-01 |
| | | | | | | | 4502175N-01 |
| | | | | | | | 4502027N-01 |

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| Pencan | 4532703N | | | | | | |
| Pencan | 4532705N | | | | | | 4502124N-01 |
| Pencan | 4532706N | | | | | | 4502125N-01 |
| Pencan | 4502035-13 | 4039239000000085938 | | | | | 4502132N-01 |
| Pencan | 4502167-13 | G1 012974 0607; | 2024-05-26 | TÜV SÜD Product Service GmbH (NB0123) | TÜV SÜD Product Service GmbH (NB0123) | 2027-12-31 | N/A |
| Pencan | 4502159-13 | G7 012974 0592; NB0123 | 2024-05-26 | TÜV SÜD Product Service GmbH (NB0123) | TÜV SÜD Product Service GmbH (NB0123) | 2027-12-31 | |
| Pencan | 4502019-01 | | | | | | |
| Pencan | 4502019-10 | | | | | | |
| Pencan | 4502043-13 | | | | | | |
| Pencan | 4502116-13 | | | | | | |
| Pencan | 4502120-13 | | | | | | |

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| Pencan | 4502175-13 | | | | | | |
| Pencan | 4502027-01 | | | | | | |
| Pencan | 4502027-10 | | | | | | |
| Pencan | 4502051-13 | | | | | | |
| Pencan | 4502124-13 | | | | | | |
| Pencan | 4502132-13 | | | | | | |
| Spinocan® | 4501373-13 | | | | | | |
| Spinocan® | 4501390-01 | | | | | | |
| Spinocan® | 4501390-10 | | | | | | |
| Spinocan® | 4501144-13 | | | | | | |
| Spinocan® | 4501195-13 | | | | | | |
| Spinocan® | 4509757-13 | | | | | | |
| Spinocan® | 4509900-01 | | | | | | |
| Spinocan® | 4509900-10 | | | | | | |
| Spinocan® | 4507401-13 | | | | | | |
| Spinocan® | 4507754-13 | | | | | | |
| Spinocan® | 4507908-01 | | | | | | |
| Spinocan® | 4507908-10 | | | | | | |

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| Article name | Article Number (under MDR application) | | | | | | |
| Spinocan® | 4506090-13 | Basic UDI-DI (under MDR application) | | | | | |
| Spinocan® | 4506014-03 | | | | | | |
| Spinocan® | 4505751-01 | | | | | | |
| Spinocan® | 4505751-10 | | | | | | |
| Spinocan® | 4505905-01 | | | | | | |
| Spinocan® | 4505905-10 | | | | | | |
| Spinocan® | 4505913-13 | | | | | | |
| Spinocan® | 4502906-01 | | | | | | |
| Spinocan® | 4502906-10 | | | | | | |
| Spinocan® | 4504917-13 | | | | | | |
| Spinocan® | 4503902-01 | | | | | | |
| Spinocan® | 4503902-10 | | | | | | |
| Spinocan® | 4502140-13 | | | | | | |
| Spinocan® | 4501900-13 | | | | | | |
| Spinocan® | 4501918-13 | | | | | | |
| Perican | 4512453 | 40392390000023912R | G1 012974 0607; | 2024-05-26 | TÜV SÜD Product Service GmbH (NB0123) | 2027-12-31 | N/A |

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| Article name | Article Number (under MDR application) | Basic UDI-DI (under MDR application) | | | | | |
| Perican | 4512200 | G7 012974 0612; NB0123 | | | | | |
| Perican | 4512383 | | | | | | |
| Perican | 4512588 | | | | | | |
| Perican | 4512782 | | | | | | |
| Perican Paed | 4502078 | | | | | | |
| Perican Paed | 4502094 | | | | | | |
| Perican Paed | 4502302 | | | | | | |
| Perican NRFit | 4512383N-01 | | | | | | |
| Perican NRFit | 4512200N-01 | | | | | | |
| Perican NRFit | 4512782N-01 | | | | | | |
| Perican NRFit | 4512453N-01 | TÜV SÜD Product Service GmbH (NB0123) | | | | | |

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|---|--|--------------------------------------|--|---|---|--|---|--------------------------------------|
| Article name | Article Number (under MDR application) | Basic UDI-DI (under MDR application) | | | | | | |
| Perican NRFit | 4512785N-01 | 403923900000027953M | G1 012974 0607; G7 012974 0612; NB0123 | 2024-05-26 2024-05-26 | TÜV SÜD Product Service GmbH (NB0123) TÜV SÜD Product Service GmbH (NB0123) | TÜV SÜD Product Service GmbH (NB0123) TÜV SÜD Product Service GmbH (NB0123) | 2027-12-31 2027-12-31 | N/A |
| Perican NRFit | 4512784N-01 | | | | | | | |
| Perican Paed NRFit | 4502078N-01 | | | | | | | |
| Perican Paed NRFit | 4502094N-01 | | | | | | | |
| Perican Paed NRFit | 4502302N-01 | | | | | | | |
| Epican Paed | 4502400 | | | | | | | |
| Epican Paed | 4502418 | | | | | | | |
| Epican Paed | 4502426 | | | | | | | |
| Epican Paed NRFit | 4502400N-01 | | | | | | | |
| Epican Paed NRFit | 4502418N-01 | | | | | | | |

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| Article name | Article Number (under MDR application) | Basic UDI-DI (under MDR application) | | | | | | |
| Epican Paed NRFit | 4502426N-01 | | | | | | | |

Effective

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Effective

Document History

| Version | Description of Change |
|---------|-----------------------|
| 1.0 | Initial version |

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This document is signed electronically in compliance with the B. Braun electronic signature policies and procedures by following persons:

UserName: Voelske, Rebecca (voelrede)
Title: Head of RA Product Mgmt. Inf. Therapy
Date: Monday, 29 April 2024, 15:05 W. Europe Daylight Time
Meaning: Document signed as Author
=====

UserName: Brand, Thomas (brantode)
Title: HC-QM-DE08 Vice President QM for non-active Medical Devices
Date: Monday, 29 April 2024, 15:41 W. Europe Daylight Time
Meaning: Approve Document
=====

UserName: Seidel, Stefan (seidstde)
Title: Head of Regulatory Affairs CoE Infusion & Pain Therapy
Date: Tuesday, 30 April 2024, 10:49 W. Europe Daylight Time
Meaning: Approve Document
=====

UserName: Ritz, Frank (ritzfrde)
Title: HC-QM DE08 Head QM CoE Pharmaceuticals
Date: Thursday, 02 May 2024, 09:18 W. Europe Daylight Time
Meaning: Approve Document
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UserName: Buenger, Joachim (buenjode)
Title: Director Template & Submission Mgmt
Date: Monday, 06 May 2024, 07:01 W. Europe Daylight Time
Meaning: Approve Document
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Title: BBMAG_LM_confirmation letter_ Regulation EU 2023/607_G12 Initiator: Anja Mai

This document is signed electronically in compliance with the B. Braun electronic signature policies and procedures by following persons:

UserName: Meyer, Frank (meyefrde)
Title: HC-QM-DE08 Vice President QM Applications Hospital Care
Date: Monday, 06 May 2024, 12:52 W. Europe Daylight Time
Meaning: Final Release of the Document
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B. Braun Melsungen AG - Document No.: G12 - Version: 1.0 - Document ID: RE-QM-DIV-000445 - Effective Date: 2024-05-06
Title: BBMAG_LM_confirmation letter_ Regulation EU 2023/607_G12

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