

TÜV Rheinland Italia S.r.l.
Sicurezza e Qualità Prodotto

TÜV Rheinland Italia S.r.l.
Via Mattei 3
20005 Pogliano Milanese (MI)
Italia

Via del Faggiolo 1/12
40132 Bologna
Italia

Aries S.r.l
Registered Headquarter:
Via XXV Luglio 43
41037 Mirandola (MO)
Operational Headquarter:
Via XXV Luglio 43,49/51,41
41037 Mirandola (MO)

Attention:
Dott.ssa Chiara Cuoghi

Date: 12/09/2024

Object: 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 (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices

Dear Dott.ssa Cuoghi,

This letter confirms that, TUV RHEINLAND ITALIA, a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number 1936 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:

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Via XXV Luglio 43 - 41037 Mirandola (MO)
Operational Headquarter:
Via XXV Luglio 43, 49/51,41 - 41037 Mirandola (MO)

The devices covered by the formal application and the written agreement mentioned above are identified in the Table below

The table identifies the devices for which an MDR application has been received and a written agreement concluded, but the NB has not yet taken the responsibility for appropriate surveillance of the corresponding devices under the applicable Directive..

In the case of devices covered by certificates issued or Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been

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Fax: +39.02.939.687.23
E-mail:informazioni@it.tuv.com
Web:www.tuvitalia.com

Capitale sociale
EURO 51.000,00 int. versato
C.C.I.A.A. Milano No. 1535451
Registro Milano No. 214918
CF e IVA 12184570153

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withdrawn, this letter also confirms that the manufacturer signed the written agreement under MDR by the date of MDD certificate expiry.

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 (EU) 2023/607), are shown below:

- 26 May 2026 for Class III custom-made implantable devices
- 31 December 2027 for Class III devices and 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)
- 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

31 December 2028 for devices not requiring the involvement of a notified body under MDD but requiring it under MDR (e.g., class I devices that qualify as re-usable surgical instruments)

Devices covered by this letter, and for which the NB is NOT responsible for appropriate surveillance of the corresponding devices under the applicable Directive, and identified on the basis of the indications provided in the MDR application received:

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
ArieSpike BASIC UDI: 803365002FT0111T4	Classe Is		Certificate issued by TÜV SÜD Certificate no.: G2S 031848 0018 Rev. 01 Annex V Date of issue 16/02/2021 Date of expiry 26/05/2024
BioDrip BASIC UDI: 803365002FT0102T3 803365002FT0103T5 803365002FT0104T7 803365002FT0105T9 803365002FT0106TB 803365002FT0601TS 803365002FT0107TD	Classe Is		Certificate issued by TÜV SÜD Certificate no.: G2S 031848 0018 Rev. 01 Annex V Date of issue 16/02/2021 Date of expiry 26/05/2024

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BioSafe BASIC UDI: 803365002FT0114TA	Classe Is		Certificate issued by TÜV SÜD Certificate no.: G2S 031848 0018 Rev. 01 Annex V Date of issue 16/02/2021 Date of expiry 26/05/2024
ChemoDrip BASIC UDI: 803365002FT0102T3 803365002FT0104T7	Classe Is		Certificate issued by TÜV SÜD Certificate no.: G2S 031848 0018 Rev. 01 Annex V Date of issue 16/02/2021 Date of expiry 26/05/2024
Droval BASIC UDI: 803365002FT0111T4	Classe Is		Certificate issued by TÜV SÜD Certificate no.: G2S 031848 0018 Rev. 01 Annex V Date of issue 16/02/2021 Date of expiry 26/05/2024
Eval BASIC UDI: 803365002FT1001T3 803365002FT1002T	Classe Is		Certificate issued by TÜV SÜD Certificate no.: G2S 031848 0018 Rev. 01 Annex V Date of issue 16/02/2021 Date of expiry 26/05/2024
Three Stop BASIC UDI: 803365002FT0101SZ 803365002FT0104T7 803365002FT0106TB 803365002FT0108TF 803365002FT0109TH 803365002FT0110T2 803365002FT0112T6 803365002FT0113T8 803365002FT0114TA 803365002FT0115TC	Classe Is		Certificate issued by TÜV SÜD Certificate no.: G2S 031848 0018 Rev. 01 Annex V Date of issue 16/02/2021 Date of expiry 26/05/2024

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AriDren BASIC UDI: 803365002FT0401TG 803365002FT0402TJ 803365002FT0403TL 803365002FT0404TN 803365002FT0405TQ 803365002FT0406TS 803365002FT0502TP 803365002FT0503TR	Classe IIa	N/A	Certificate issued by TÜV SÜD Certificate no.: G2S 031848 0018 Rev. 01 Annex V Date of issue 16/02/2021 Date of expiry 26/05/2024
Biodrip BASIC UDI: 803365002FT0208TL	Classe IIa	N/A	Certificate issued by TÜV SÜD Certificate no.: G2 031848 0017 Rev. 01 Annex V Date of issue 16/02/2021 Date of expiry 26/05/2024
BioRet BASIC UDI: 803365002FT0301TB 803365002FT0302TD 803365002FT0303FT 803365002FT0304TH	Classe IIa	N/A	Certificate issued by TÜV SÜD Certificate no.: G2 031848 0017 Rev. 01 Annex V Date of issue 16/02/2021 Date of expiry 26/05/2024
ChemoDrip BASIC UDI: 803365002FT0201T6	Classe IIa	N/A	Certificate issued by TÜV SÜD Certificate no.: G2 031848 0017 Rev. 01 Annex V Date of issue 16/02/2021 Date of expiry 26/05/2024
Three Stop BASIC UDI: 803365002FT0106TB 803365002FT0203TA 803365002FT0202T8 803365002FT0204TC 803365002FT0205TE 803365002FT0209TN	Classe IIa	N/A	Certificate issued by TÜV SÜD Certificate no.: G2 031848 0017 Rev. 01 Annex V Date of issue 16/02/2021 Date of expiry 26/05/2024

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Three stop BASIC UDI-DI 803365002FT0801U4	Class Im	N/A	Certificate issued by TÜV SÜD Certificate no.: G2MS 031848 0020 Rev. 00 Annex V Date of issue 22/02/2021 Date of expiry 26/05/2024
WEIGHTFLOW BASIC UDI-DI 803365002FT0701TX	Class Im	N/A	Certificate issued by TÜV Rheinland Italia S.r.l. Certificate no.: DD 60136132 Annex V Date of issue 19/03/2019 Date of expiry 18/03/2024

In detail, this Confirmation Letter **only covers** the REFs (Product Codes) listed in the ***Annex 5: Elenco lettera di proroga con codici_Rev.01***

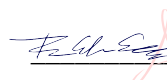
Any other code not listed in this documentation **is not covered** by this Confirmation Letter.

TUV RHEINLAND ITALIA (n.1936)

Notified body
Ing. Lisa Menarini

 Firmato digitalmente da
Lisa Menarini

Notified body
Ing. Francesco Elia Sansonne

 Firmato digitalmente
da Francesco Elia
Sansonne

Annex:

- Annex 1: Certificate No. G2S 031848 0018 Rev. 01 issued by TÜV SÜD
- Annex 2: Certificate No. G2 031848 0017 Rev. 01 issued by TÜV SÜD
- Annex 3: Certificate No. G2MS 031848 0020 Rev. 00 issued by TÜV SÜD
- Annex 4: Certificate No. DD 60136132 issued by TÜV Rheinland Italia S.r.l.
- Annex 5: Elenco lettera di proroga con codici_Rev.01

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