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

KNOW MEDICAL S.r.l.
Via Giuseppe Verdi 15 - 46019
Viadana (MN)

Attention:
To whom it may concern

Notified Body Confirmation Letter
Date: 22/12/2025
Project n°: 7987408

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

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Dear all,

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:

KNOW MEDICAL S.r.l.
Resistered office: Via Giuseppe Verdi 15 - 46019 Viadana (MN) – Italy
Operational site: Via Guido Rossa, 36 - Z.I. Gerbolina - 46019 Viadana (MN) - Italy

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 and the NB is also responsible, since 26 September 2024, 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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EURO 51.000,00 int. versato
C.C.I.A.A. Milano No. 1535451
Registro Milano No. 214918
CF e IVA 12184570153

withdrawn, this letter also confirms that the manufacturer signed the written agreement under MDR by the date of MDD certificate expiry.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 responsible, since 26 September 2024, 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**
Huber needles BASIC UDI 804903319HUBERNDLZS	IIa	Sterile Huber needles Ref codes.: HNxggyyzzO	Certificate issued by: ICIM (NB n°0425) Certificate n° 0425-MED-002364-02 Annex V Date of issue: 27/04/2021 Date of expiry: 26/05/2024
Infusion and transfusion set and accessories (infusion set, transfusion set, burette, extension lines, connectors), Set for urology arthroscopy and laparoscopy, sets for antiblastic solutions. BASIC UDI 804903319INFUSION6G.	IIa and Is	Infusion and transfusion set and accessories (infusion set, transfusion set, burette, extension lines, connectors) Ref codes.: IS XXXXYY O TS XXXXYY O BG XXXX YY O FL1 XXX O	Certificate issued by: Istituto Superiore di Sanità (NB n°0373) Certificate n° QCT-0164-21 Addendum nr 01-21 e Addendum nr 05-21 Annex II excluded pt. 4 Date of issue: 02/03/2021

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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
		Set for urology arthroscopy and laparoscopy, sterile Ref codes.: EL XXXX YY O	Date of expiry: 26/05/2024
		Oncofux - sets for antiblastic solutions Ref codes.: FL2 xxx O	Certificate issued by: ICIM (NB n°0425) Certificate n° 0425-MED-002364-02 Annex V Date of issue: 27/04/2021 Date of expiry: 26/05/2024
Drainage catheters and accessories BASIC UDI 804903319DRAINAGETQ	IIa and Is	Drainage catheters and accessories Ref codes.: XYKJJWW, XYKJJWWZZZHHQ, XYZKKKJJJ	Certificate issued by: Istituto Superiore di Sanità (NB n°0373) Certificate n° QCT-0164-21 Addendum nr 02-21 Annex II excluded pt. 4 Date of issue: 02/03/2021 Date of expiry: 26/05/2024
Parenteral oncology and enteral nutrition bags BASIC UDI 804903319ENTPARBAGK3	IIa and Is	Parenteral oncology and enteral nutrition bags Ref codes.: PB XXXX YY O, EB XXXX YY O, FL2 XXX O	Certificate issued by: Istituto Superiore di Sanità (NB n°0373) Certificate n° QCT-0164-21 Addendum nr 04-21 Annex II excluded pt. 4 Date of issue: 02/03/2021 Date of expiry: 26/05/2024
Surgical Kits BASIC UDI 804903319CUSTPACK8C.	IIa and Is	Surgical Kits Ref codes.: KITxxxO	Certificate issued by: ICIM (NB n°0425) Certificate n° 0425-MED-002364-02 Annex V Date of issue: 27/04/2021 Date of expiry: 26/05/2024

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In agreement with the documentation provided by the manufacturer, the Notified Body declares that:

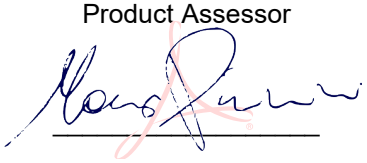
- the following Medical Devices, included in the certificate released by Istituto Superiore di Sanità (NB n°0373), QCT-0164-21 Addendum nr 11-11 and Addendum nr 03-21, Annex II excl. pt. 4, issue date: 02/03/2021 expiry date: 26/05/2024, **are not included and are not covered** by this confirmation letter:
    - Needles, sterile (IV cannula, fistula, venous and epicranic needle) Ref. codes: Needles cannula IC X YYY O, Needles fistula FN XX YY KK WWW O, Needles venous AV X YYY O, Needles epicranic AF X YYY O).
    - Syringes, sterile Ref codes.: SY Z XXX O.
- the following Medical Devices, included in the certificate released by ICIM (NB n°0425), number: 0425-MED-002364-02, Annex V, issue date: 27/04/2021 expiry date: 26/05/2024, **are not included and are not covered** by this confirmation letter:
    - Set with leukocyte filter, Ref codes: LRF xxx O.
    - Elastomeric Pumps Ref codes.: ES0 xxx O, ES1 xxx O.

Furthermore, considering the nature of the open alphanumeric codes related to the devices Kit Procedurali ref. KITxxxO, certificate n°0425-MED-002364-02 issued by ICIM (NB n°0425), that allows multi coding and multiple configurations and in accordance with the documents provided by the manufacturer, the ON declares that the kits manufacturer with the components below **are not included and are not covered** by this Confirmation letter:

- Disinfectant wipes for non-invasive medical devices
- Single use surgical scalpels

On behalf oft he Notified Body
TUV RHEINLAND ITALIA (n.1936)

Marco Piccinini
Product Assessor



Annex:
Certificate No. 0425-MED-002364-02 issued by ICIM (NB n°0425)
Annex: Certificate No. QCT-0164-21 and cited addendum issued by Istituto Superiore di Sanità (NB n°0373)

Revision History

Date	Revision index	Reason
28/05/2024	0	First issue
05/12/2024	1	Update of ON obligations
22/12/2025	2	Products covered by this confirmation letter have been updated according to Know Medical renunciation letter dated 18/12/2025 and MDR application revision 1 dated 11/12/2025.

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