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

PERISO SA
Via Senago 42D
6912 Pazzallo (CH)
Svizzera

Attention:
Mr Santoli

Date: 27.06.2023

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 Mr Santoli,

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::

PERISO SA
Via Senago 42D
6912 Pazzallo (CH)
Svizzera

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 under Directive 90/385/EEC (AIMDD) or Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the manufacturer signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry; or provided evidence that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 the 20 Mar 2023 for the relevant devices.

TÜV Rheinland Italia S.r.l.
Sede Legale ed operativa
Membro del Gruppo
TÜV Rheinland

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

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**
CTU MEGA 20 **BASIC UDI 7649990767CME20LE**	Classe IIa	N/A	Certificate BSI N. CE670385 Issued 2018-07-19 Expiry date 2023-07-18 Allegato II escluso p.to 4
CTU S WAVE **BASIC UDI 7649990767SWAVEXZ**	Classe IIa	N/A	Certificate BSI N. CE670385 Issued 2018-07-19 Expiry date 2023-07-18 Annex II excluding sec. 4

TUV RHEINLAND ITALIA (n.1936)

Massimiliano Testi
Local Field Manager

Annex: Certificate of BSI n. CE 670385

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