

**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 transitional provisions for certain medical devices**

# TUV Rheinland Italia

Dear Mr Santoli,

# Seguridad y calidad del p

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 provided appropriate surveillance of the corresponding device

TÜV Rheinland Italia S.r.l.  
Sede legale ed operativa

In the case of devices covered by certificates issued under Directive 90/269/EEC (AIMDD) or Directive 93/42/EEC (MDD) that expired March 2023, without having been withdrawn, this manufacturer signed the written agreement under MDR at the time of certificate expiry; or provided evidence that a competent authority had granted a derogation or exemption from the application procedure in accordance with Article 59(1) of MDR, respectively, by the 20 Mar 2023 for the relevant device

# TUV Rheinland Ital

# Via Senago 42D Via Ma

# 20005 Pogliano Milanese

# Italia Suiza

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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 device is a custom-made device	MDI dev
<b>CTU MEGA 20</b>  <b>BASIC UDI</b> <b>7649990767CME20LE</b>	Classe IIa	N/A	Certificate BSI N. CE670385 Issued 2018-07-19  Expiry date 2023-07-18  Allegato II escluso p.to 4
<b>CTU S WAVE</b>  <b>BASIC UDI</b> <b>7649990767SWAVEXZ</b>	Classe IIa	N/A	Certificate BSI N. CE670385

TUV RHEINLAND ITALIA (n.1936)

Annex: Certificate of BSI n. CE 670385

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**Los plazos de transición o**  
**el cumplimiento continuo**  
**120.3c del MDR (modif**

**26 de mayo d**

**31 de diciemb**

**excluyendo te**