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

TÜV Rheinland Italia S.r.l.
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40132 Bologna
Italia

RUNNER S.R.L.
Registered and Operational Headquarter:
Via G. di Vittorio 391
41032 Cavezzo (MO) – Italia

C.A. Dott. Pierluigi Loscalzo

Date: 2024/01/31

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 Dott. Loscalzo

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:

RUNNER S.R.L.
Registered and Operational Headquarter:
Via G. di Vittorio 391, 41032 Cavezzo (MO) – Italia

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 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issued or Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the manufacturer signed the written agreement under MDR by the date of MDD certificate expiry.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

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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

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 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
Vertical cycle ergometers for rehabilitation **BASIC UDI-DI** **805383912FT01CF** **Models:** **RUN700/T** **RUN700/TR** **RUN1400/T** **RUN1400/TR**	Class IIa	N/A	Certificate issued by TUV RHEINLAND ITALIA Certificate No. HD 60149833 Annex II except p.4 Issued by 21/09/2020 Expiry by 26/05/2024
Treadmills for motor rehabilitation **BASIC UDI-DI** **805383912FT02CH** **Models:** **RUN2011T** **RUN2011/T-PC** **RUN2011/TR-PC** **RUN2011/TRO-PC** **RUN2011/TJ-PC** **RUN2011/TJO-PC** **RUN7410T** **RUN7410/T-PC** **RUN7410/TR-PC** **RUN7410/TJ-PC** **RUN7410/TJ XL-PC** **RUN7411/T-PC** **RUN7411/TR-PC** **RUN7411/TJ-PC** **XR450R** **XR450M** **XR450P** **XR600R**	Class IIa	N/A	Certificate issued by TUV RHEINLAND ITALIA Certificate No. HD 60149833 Annex II except p.4 Issued by 21/09/2020 Expiry by 26/05/2024

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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
XR600M **XR600P** **REHARUNNER01 PC** **REHARUNNER01** **ORTOPEDICO PC** **REHARUNNER02 PC** **REHARUNNER 02/70 PC**			

TUV RHEINLAND ITALIA (n.1936)

Ing. Lisa Menarini
Project Manager

Firmato digitalmente da Lisa Menarini

Annex: Certificate No. **HD 60149833**
issued by TUV RHEINLAND ITALIA

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