

## Manufacturer's declaration

in relation to Regulation (EU) 2023/607 which amends Regulations (EU) 2017/745 and (EU) 2017/746 regarding the transitional provisions for certain medical devices and in vitro diagnostic medical devices, in particular with regard to

- the validity of certificates issued pursuant to Council Directive 90/385/EEC on active implantable medical devices (AIMDD) or Council Directive 93/42/EEC on medical devices (MDD) (Directive Certificates) and/or<sup>1</sup>
- their manufacturers with the conditions for continued placing on the market and commissioning

Manufacturer's name	<b>RUNNER SRL</b>
Manufacturer's address and contact details	Via G. di Vittorio 391, 41032 Cavezzo (MO) – Italy
Unique Registration Number (SRN) (if available)	IT-MF-000029314

Name of the notified body (if applicable)	TÜV Rheinland Italia Srl
Notified body number (if applicable)	1936
Directive certificate number(s) to which this confirmation is made (if applicable)	HD 60149833
Original expiry date as indicated on the Directive Certificate before validity extension (if applicable)	05/26/2024
End date of extended validity / transition period	12/31/2028

<sup>1</sup>The first condition is not applicable in the case of devices for which the conformity assessment procedure under the MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up before 26 May 2021 and for for which the conformity assessment procedure under this Regulation requires the involvement of a notified body.

We, as manufacturers, declare under our sole responsibility:

- for the Directive Certificate listed above (or see the attached program, in case of multiple certificates) the conditions for the legal extension of validity as required by article 120.2 of the MDR and
- the devices listed in the attached table and we as their manufacturers comply with the conditions listed in Article 120.3c of the MDR for continued placing on the market and putting into service,

that is, satisfying the following conditions:

➤ **Directive Certificate as listed above or in the attached syllabus.**

The directive certificates for the listed devices were issued after May 25, 2017, were valid on May 26, 2021, and have not been withdrawn since.

- Expires *after* March 20, 2023, and:

One or more formal applications to the notified body in accordance with section 4.3, first paragraph of Annex VII MDR for conformity assessment have been submitted or will be submitted by us to a notified body by 26 May 2024 for the devices listed in the attached table or their replacements and signed written agreements are/will be installed in accordance with Section 4.3, second paragraph of Annex VII MDR before 26 September 2024.

➤ **Quality Management System (QMS)**

A quality management system is in place in accordance with Article 10(9) of the MDR.

➤ **Devices as listed in the plan attached.**

- Devices continue to comply with AIMDD or MDD.
- There are no significant changes in the design and intended use.
- The devices do not present unacceptable risks to the health or safety of patients, users or other persons, or to other aspects of public health protection.

**Signed in the name and on behalf of the manufacturer:**

Full company name: RUNNER SRL

Location and date: Cavezzo (MO), 03/26/2024

Signature , printed name , title



Pierluigi Loscalzo, PRRC

Contact details (at least email):

Pierluigi Loscalzo

[piero@runneritaly.it](mailto:piero@runneritaly.it)

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## List of devices

The Manufacturer's Declaration above is valid for the following devices:

Identification of devices <sup>2</sup> ( for example, device name, family/group name, device model, or catalog number)	Director Certificate number to which this confirmation is made ( if applicable)	Original expiry date as indicated on the Directive Certificate prior to extension of validity (if applicable)	Name and number of the notified body that issued the Directive certificate (if applicable)	Name and number of the notified body where the MDR application/signed contract was submitted (if applicable)	End date of extended validity / transition period	Replacement devices (if applicable)
<b>RUN700/T</b>	HD 60149833	05/26/2024	TÜV Rheinland Italia Srl, N°1936	TÜV Rheinland Italia Srl, N°1936	December 31, 2028 (Class IIa)	<b>NA</b>
<b>RUN700/TR</b>	HD 60149833	05/26/2024	TÜV Rheinland Italia Srl, N°1936	TÜV Rheinland Italia Srl, N°1936	December 31, 2028 (Class IIa)	<b>NA</b>
<b>RUN1400/T</b>	HD 60149833	05/26/2024	TÜV Rheinland Italia Srl, N°1936	TÜV Rheinland Italia Srl, N°1936	December 31, 2028 (Class IIa)	<b>NA</b>
<b>RUN1400/TR</b>	HD 60149833	05/26/2024	TÜV Rheinland Italia Srl, N°1936	TÜV Rheinland Italia Srl, N°1936	December 31, 2028 (Class IIa)	<b>NA</b>
<b>RUN2011T</b>	HD 60149833	05/26/2024	TÜV Rheinland Italia Srl, N°1936	TÜV Rheinland Italia Srl, N°1936	December 31, 2028 (Class IIa)	<b>NA</b>

<sup>2</sup> for devices with AIMDD/MDD certificate(s) the identification should be as in the certificate and only if the certificate has a generic purpose it should be as defined above)

<b>RUN2011/T-PC</b>	HD 60149833	05/26/2024	TÜV Rheinland Italia Srl, N°1936	TÜV Rheinland Italia Srl, N°1936	December 31, 2028 (Class IIa)	<b>NA</b>
<b>RUN2011/TR-PC</b>	HD 60149833	05/26/2024	TÜV Rheinland Italia Srl, N°1936	TÜV Rheinland Italia Srl, N°1936	December 31, 2028 (Class IIa)	<b>NA</b>
<b>RUN2011/TRO-PC</b>	HD 60149833	05/26/2024	TÜV Rheinland Italia Srl, N°1936	TÜV Rheinland Italia Srl, N°1936	December 31, 2028 (Class IIa)	<b>NA</b>
<b>RUN2011/TJ-PC</b>	HD 60149833	05/26/2024	TÜV Rheinland Italia Srl, N°1936	TÜV Rheinland Italia Srl, N°1936	December 31, 2028 (Class IIa)	<b>NA</b>
<b>RUN2011/TJO-PC</b>	HD 60149833	05/26/2024	TÜV Rheinland Italia Srl, N°1936	TÜV Rheinland Italia Srl, N°1936	December 31, 2028 (Class IIa)	<b>NA</b>
<b>RUN7410T</b>	HD 60149833	05/26/2024	TÜV Rheinland Italia Srl, N°1936	TÜV Rheinland Italia Srl, N°1936	December 31, 2028 (Class IIa)	<b>NA</b>
<b>RUN7410/T-PC</b>	HD 60149833	05/26/2024	TÜV Rheinland Italia Srl, N°1936	TÜV Rheinland Italia Srl, N°1936	December 31, 2028 (Class IIa)	<b>NA</b>
<b>RUN7410/TR-PC</b>	HD 60149833	05/26/2024	TÜV Rheinland Italia Srl, N°1936	TÜV Rheinland Italia Srl, N°1936	December 31, 2028 (Class IIa)	<b>NA</b>

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<b>RUN7410/TJ-PC</b>	HD 60149833	05/26/2024	TÜV Rheinland Italia Srl, N°1936	TÜV Rheinland Italia Srl, N°1936	December 31, 2028 (Class IIa)	<b>NA</b>
<b>RUN7410/TJ XL-PC</b>	HD 60149833	05/26/2024	TÜV Rheinland Italia Srl, N°1936	TÜV Rheinland Italia Srl, N°1936	December 31, 2028 (Class IIa)	<b>NA</b>
<b>RUN7411/T-PC</b>	HD 60149833	05/26/2024	TÜV Rheinland Italia Srl, N°1936	TÜV Rheinland Italia Srl, N°1936	December 31, 2028 (Class IIa)	<b>NA</b>
<b>RUN7411/TR-PC</b>	HD 60149833	05/26/2024	TÜV Rheinland Italia Srl, N°1936	TÜV Rheinland Italia Srl, N°1936	December 31, 2028 (Class IIa)	<b>NA</b>
<b>XR450R</b>	HD 60149833	05/26/2024	TÜV Rheinland Italia Srl, N°1936	TÜV Rheinland Italia Srl, N°1936	December 31, 2028 (Class IIa)	<b>NA</b>
<b>XR450M</b>	HD 60149833	05/26/2024	TÜV Rheinland Italia Srl, N°1936	TÜV Rheinland Italia Srl, N°1936	December 31, 2028 (Class IIa)	<b>NA</b>
<b>XR450P</b>	HD 60149833	05/26/2024	TÜV Rheinland Italia Srl, N°1936	TÜV Rheinland Italia Srl, N°1936	December 31, 2028 (Class IIa)	<b>NA</b>
<b>XR600R</b>	HD 60149833	05/26/2024	TÜV Rheinland Italia Srl, N°1936	TÜV Rheinland Italia Srl, N°1936	December 31, 2028 (Class IIa)	<b>NA</b>
<b>XR600M</b>	HD 60149833	05/26/2024	TÜV Rheinland Italia Srl, N°1936	TÜV Rheinland Italia Srl, N°1936	December 31, 2028 (Class IIa)	<b>NA</b>
<b>XR600P</b>	HD 60149833	05/26/2024	TÜV Rheinland Italia Srl, N°1936	TÜV Rheinland Italia Srl, N°1936	December 31, 2028 (Class IIa)	<b>NA</b>

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REHARUNNER01 PC	HD 60149833	05/26/2024	TÜV Rheinland Italia Srl, N°1936	TÜV Rheinland Italia Srl, N°1936	December 31, 2028 (Class IIa)	<b>NA</b>
REHARUNNER01 ORTHOPEDIC PC	HD 60149833	05/26/2024	TÜV Rheinland Italia Srl, N°1936	TÜV Rheinland Italia Srl, N°1936	December 31, 2028 (Class IIa)	<b>NA</b>
REHARUNNER02 PC	HD 60149833	05/26/2024	TÜV Rheinland Italia Srl, N°1936	TÜV Rheinland Italia Srl, N°1936	December 31, 2028 (Class IIa)	<b>NA</b>
REHARUNNER 02/70 PC	HD 60149833	05/26/2024	TÜV Rheinland Italia Srl, N°1936	TÜV Rheinland Italia Srl, N°1936	December 31, 2028 (Class IIa)	<b>NA</b>

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