DICHIARAZIONE DI CONFORMITÁ (EU) / *(UE) DECLARATION OF CONFORMITY*

Fabbricante: *Manufacturer:*	RIMEC S.r.l.
Numero di Registrazione Unico (art.31): *Single Registration Number – SRN, (art.31):*	IT-MF-000036619
Dispositivo Medico: *Medical Device:*	FISIOTEK: Dispositivo medico per la riabilitazione passiva dell'arto superiore/inferiore *Medical Device for passive rehabilitation of the upper/lower limb*
UDI-DI Base: *Basic UDI-DI:*	805361095AGPRB4
Modelli/Codici: *REF. code:*	Allegato A / *Annex A*
Codice EMDN-Destinazione d'uso: *EMDN code-Intended Use:*	Z120603 – APPARECCHIATURE PER GINNASTICA PASSIVA RIABILITATIVA/ PASSIVE REHABILITATIVE GYMNASTICS EQUIPMENT
Classificazione/*Classification*: **Allegato VIII/** *Annex VIII* **– MDR 2017/745:** **Annex IX/** *Annex IX* **– MDD 93/42/CEE:**	Classe di Rischio IIa – Regola Applicata 09 *Risk Class IIa – Applied Rule 09*
Regolamenti / Direttive / Standard applicati: *Applicable Regulation / Directive / Standard:*	Allegato B / Annex B
Organismo Notificato: *Notified Body:*	1370 – Bureau Veritas
Certificato CE n°: *EC Certificate n°:*	IT268804-1

RIMEC s.r.l. con sede legale in Località Braine 57/A-40036 Rioveggio (BO) ITALIA, fabbricante della famiglia di dispositivi denominati "Fisiotek", dichiara sotto la propria responsabilità, che i dispositivi soddisfano tutti i requisiti generali di sicurezza e prestazione richiesti dalla Direttiva della Comunità Europea 93/42/CEE sui Dispositivi Medici.
La procedura per la marcatura CE è stata eseguita in accordo alle prescrizioni dell'Allegato V (Valutazione della Conformità basata sul sistema di gestione della qualità e sulla valutazione della documentazione tecnica) – Certificato CE conforme ai requisiti previsti dalla DIRETTIVA 93/42/CEE e s.m.i. no.IT268804-1 valido sino a 26-05-2023.
RIMEC ha presentato formale domanda di certificazione all'ente notificato Bureau Veritas (1370) secondo il nuovo Regolamento MDR 2017/745, del Parlamento Europeo e del Consigli, del 5 aprile 2017. Rispondendo ai requisiti necessari, la validità del certificato MDD n. IT268804-1 è prorogata fino al 31/12/2028 dalla Confirmation Letter rilasciata dall'organismo notificato Bureau Veritas, identificato dal numero 1370 in NANDO (Banca dati Organismi Notificati UE), secondo quanto previsto dal Regolamento (UE) 2023/607 del parlamento Europeo e del Consiglio del 15 marzo 2023.

RIMEC s.r.l. *with its registered office at Località Braine 57/A-40036 Rioveggi (BO), ITALY, as the manufacturer of the famility of devices named "Fisiotek", hereby declares, under its own responsibility, that the devices meet all the general safety and performance requirements set out by the European Community Directive 93/42/EEC on Medical Devices. The procedure for CE marking was carried out in accordance with the provisions of Annex V (Conformity Assessment based on the quality management system and evaluation of the technical documentation) – CE Certificate in compliance with the requirements of DIRECTIVE 93/42/EEC and its amendments, no. IT268804-1, valid until 26-05-2023.*
RIMEC has formally submitted an application for certification to the notified body Bureau Veritas (1370) under the new MDR Regulation 2017/745, of the European Parliament and Council, dated 5 April 2017. Having met the necessary requirements, the validity of MDD certificate no. IT268804-1, has been extended until 31/12/2028 by the Confirmation Letter issued by the notified body Bureau Veritas, identified by the number 1370 in NANDO (EU Notified Bodies Database), in accordance with Regulation (EU) 2023/607 of the European Parliament and Council dated 15 March 2023.

Modello *Model*	Fisiotek LT-5R, LTG-5R, LTP-5R
Matricola *Serial Number*	
Luogo e Data di emissione / *Place and Date of Issued:*	Rioveggio,24/02/2025

Digitally signed by Cobzari-Ţurcan Rodica
Date: 2025.12.22 14:04:15 EET
Reason: MoldSign Signature
Location: Moldova
MOLDOVA EUROPEANĂ

Redatta, Verificata e Approvata da:
Issued, Verified and Approved by:

SILVIA BIANCHI
Legale Rappresentante
Legal Representative

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Annex A – Lista Prodotti/Product List

Nome Modello / *Product name*	Codice prodotto / *Reference Code*
FISIOTEK 3000GS	F3GS
FISIOTEK 3000G	F3G
FISIOTEK 3000E	F3E
FISIOTEK 3000TS	F3TS
FISIOTEK 3000N	F3N
FISIOTEK LT-5R	FLT-5R
FISIOTEK LTG-5R	FLT/G-5R
FISIOTEK LTP-5R	FLT/P-5R

Annex B – Applicable Standards

Il dispositivo medico è conforme alle seguenti Norme (europee) / Regolamenti / Direttive / Specifiche / MDCG:
The device is complying with the following European standards, Regulations, Common Specification and Directive:

Documento e Versione *Document and Version*	Descrizione *Description*
Directive 93/42/CEE: 2007	Council Directive 93/42/EEC of 14 June 1993 amended by Directive 2007/47/CE concerning medical devices
Regulation (EU) 2017/745: 2017	REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC)
Regulation (EU) 2021/2226: 2021	REGULATION laying down rules for the application of Regulation (EU) 2017/745 of the European Parliament and of the Council as regards electronic instructions for use of medical devices
Directive (EU) 2019/771: 2019	Directive (EU) 2019/771 of the European Parliament and of the Council of 20 May 2019 on certain aspects concerning contracts for the sale of goods, amending Regulation (EU) 2017/2394 and Directive 2009/22/EC, and repealing Directive 1999/44/EC
Directive 2012/19/EU: 2012	Directive 2012/19/EU of the European Parliament and of the Council of 4 July 2012 on waste electrical and electronic equipment (WEEE) (recast) Text with EEA relevance
EN ISO 13485 (H): 2016/ A11:2021	Medical Devices – Quality Management Systems – Requirements for Regulatory Purposes
EN ISO 14971 (H): 2019/ A11:2021	Medical Devices – Application of Risk Management to Medical Devices
EN ISO 15223-1 (H): 2021	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements
IEC 60601-1: 2005/ A1:2012/ A2:2020 EN 60601-1: 2006/ A11:2011/ A1:2013/ A12:2014/ A2:2021	Medical electrical equipment - - Part 1: General requirements for basic safety and essential performance
IEC 60601-1-2: 2014/ A1:2020 EN 60601-1-2: 2015/ A1:2021	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and test.
IEC 60601-1-6: 2010 /A1:2013/ A2:2020 EN 60601-1-6: 2010 /A1:2015/ A2:2021	Medical electrical equipment. General requirements for basic safety and essential performance. Collateral standard: Usability
IEC 62366-1: 2015/ A1:2020 EN 62366-1: 2015/ A1:2020	Medical devices - Application of usability engineering to medical devices
IEC 62304: 2006/ A1:2015	Medical device software –Software life cycle processes