BUREAU VERITAS
Certification

RIMEC S.R.L.

Località Braine, 57/A Frazione Rioveggio - 40036 MONZUNO (BO) - ITALY

Certified site:

Località Braine, 57/A Frazione Rioveggio - 40036 MONZUNO (BO) - ITALY

Bureau Veritas Italia S.p.A. certifies that the Production Quality Assurance System of the above organization has been audited and found to be in accordance with the requirements of

DIRECTIVE 93/42/EEC

(according to Annex V)

In relation to the following products

Product subcategory :	Active rehabilitation devices and active prostheses
Generic group:	Medical devices for passive motion
Model:	Fisiotek HP2, Fisiotek LT-5R, Fisiotek 3000 GS, Fisiotek 3000 G, Fisiotek 3000 E, Fisiotek 3000 TS, Fisiotek 3000 N
Class:	IIa

Reference BV practice: ZIG. N. **60639999**

Original cycle start date: **09 June 2013**

Expiry date of previous cycle: **26 May 2020**

Certification / Recertification Audit date: **30-31 March 2020**

Certification / Recertification cycle start date: **05 May 2020**

Subject to the continued satisfactory operation of the organization's Management System, this certificate expires on: **26 May 2023**

Certificate No. - Version: IT268804-1

Revision date: 05 May 2020

ANDREA FILIPPI– Certification SL Manager

Digitally signed by Cobzari-Ţurcan Rodica
Date: 2025.12.22 14:04:41 EET
Reason: MoldSign Signature
Location: Moldova
MOLDOVA EUROPEANĂ

This certificate is issued by Bureau Veritas Italia S.p.A. Viale Monza, 347-20126 Milan, as a notified body for the Directive 93/42/EEC, with identification number 1370

Further clarifications regarding the scope of this certificate and the applicability of the management system requirements may be obtained by consulting the organisation.
To check this certificate validity please refer to the website www.bureauveritas.it

Milan, 5th July 2023
C/0385/23/GL/mab

To: RIMEC SRL
Località Braine, 57/A
Frazione Rioveggio
40036 MONZUNO (BO)

Bureau Veritas Italia SpA

Notified Body Confirmation Letter with reference to the CE Marking Certificate **n° IT268804-1 – Directive 93/42/EEC (MDD) – FLEX: 9417432**

This letter confirms that, Bureau Veritas Italia SpA, a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number 1370 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 (n. 5956708) in accordance with Section 4.3, second subparagraph of Annex VII of MDR with the following manufacturer for the devices in Table n.1:

RIMEC SRL
Località Braine, 57/A
Frazione Rioveggio
40036 MONZUNO (BO)
ITALY

Table n.1

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	Device name under MDD corresponding to the device under MDR application	MDD/AIMDD Certificate Reference(s) of the devices under MDR application
FISIOTEK LT-5R	IIa	**FISIOTEK LT-5R**	Certificate n. IT268804 – rev. 1 issued on 05th May 2020
FISIOTEK 3000 GS, FISIOTEK 3000 G, FISIOTEK 3000 E, FISIOTEK 3000 TS, FISIOTEK 3000 N	IIa	**FISIOTEK 3000 GS, FISIOTEK 3000 G, FISIOTEK 3000 E, FISIOTEK 3000 TS, FISIOTEK 3000 N**	Certificate n. IT268804 – rev. 1 issued on 05th May 2020

In accordance with EU Regulation 2023/607 of the European Parliament of the Council of 15 March 2023, Bureau Veritas Italia hereby confirms that:

a. The above-mentioned agreement (n. 5956708) was signed before the expiry date (2023/05/26) of the certificate shown in Table n.1;
b. Bureau Veritas Italia Spa is responsible for the appropriate surveillance of medical devices certified under Directive 93/42/EEC and subsequent amendments, corresponding to medical

devices for which an agreement has been signed for certification according to EU Regulation 2017/745 (MDR) as shown in table n.1

As required by EU Regulation 2023/607, the validity of the MDD certificate n. IT268804–1 is extended until 2028/12/31, assuming that the manufacturer continues to comply with all the applicable conditions specified by EU Regulation 2023/607.

Confirmation Letter Revision History

Date	Revision	Action
2023/07/05	0	Initial issue

GIORGIO LANZAFAME
Bureau Veritas Italia S.p.A.
Certification Division
LOCAL TECHNICAL
MANAGER