ORTHOLUTIONS GmbH & Co. KG
Am Oberfeld 8
D-83206 Rosenheim
GERMANY

LETTER OF APPOINTMENT
"Person responsible for regulatory compliance acc. to Article 15 MDR"

We herewith appoint Mr. Dino Gallo, CEO and Co-Founder of Orthолutions GmbH & Co. KG, as

Person responsible for regulatory compliance (PRRC)

according to Article 15 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 (**MDR**),

for the Orthолutions GmbH & Co. KG

The PRRC's duties and responsibilities are defined in **Annex 1**.

Mr. Dino Gallo hereby confirms as new PRRC

- that he accepts the office and duties of the PRRC for the Orthолutions GmbH & Co. KG as defined above and
- that she/he fulfills the necessary qualifications according to Article 15 para 1 S. 3 of MDR, which are described in detail in **Annex 2**.

Rosenheim, 13. December 2021
Place, Date

Jenny Schmid
CEO / CPO (D) Co-Founder

Signature of director or the duly authorized representative

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Rosenheim, 13. December 2021
Place, Date

Dino Gallo
CEO Dipl. CPO (D) Co-Founder

Signature of PRRC

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Annex 1

List of duties and responsibilities of the PRRC

The following duties and responsibilities refer to the following listed medical devices of Ortholutions GmbH & Co. KG:

1. Trunk orthosis in custom-made class I.
2. Orthoses of the lower and upper extremities in special design Class I.
3. Prostheses of the lower extremities in the special design Class I.
4. Custom-made foot insoles Class I.
5. Seat and reclining shells as well as orthopaedic custom-made products of all kinds.

Duties and Responsibilities according to Art. 15 para 3 MDR

1. Art. 15 para 3 (a): appropriate check of the conformity of the aforementioned devices in accordance with the quality management system under which such devices are manufactured and before such device is released
2. Art. 15 para 3 (b): drawing up and keeping up to date of the t documentation in accordance with Art. 10 par 5, Annex XIII, para 2 MP-VO
3. Art. 15 para 3 (c): fulfillment of the post-market surveillance obligations in accordance with Article 10(10)
4. Art. 15 para 3 (d): fulfillment of reporting obligations referred to in Articles 87 to 91

The PCCR will fulfill the aforementioned duties and responsibilities in compliance with all legal and regulatory requirements and in compliance with the company´s Standard Operating Procedures (SOPs) hereto.

Annex 2

List of formal qualifications of PRRC acc. to Art. 15 para 1 MDR

Evidence acc. to Art. 15 para 1 s. 3 (manufactures of custom-made devices)			
	Discipline / name and date of degree **/** **Description of professional experience, function/job title**	**university/ college, period of studies** **/** **Employer's company, period of employment**	**Original certificate or certified copy supplied as evidence** **(yes/no)**
(at least two years of professional experience within a relevant field of manufacturing			