tyromotion

Declaration of Conformity

Manufacturer
Tyromotion GmbH
Bahnhofgürtel 59, A-8020 Graz, Austria
SRN (Single Registration Number): AT-MF-000016168

Product Specification	
Article Number and Product Name	(10587) Amadeo
UDI-DI	9120077180212
Intended Purpose	The Amadeo system is intended for robot-supported finger-hand therapy of patients with neurological damage to the central nervous system, caused by typical indications such as stroke or traumatic brain injury.
Basic UDI-DI	912007718AMADEO3J
Including Software	TyroS Software Version 6.5.x
Components and Accessories	Table frame Handunit Hand- armsupport adults Hand- armsupport children Finger fix adult (á 500 pcs.) Finger fix children (á 500 pcs.) Finger tips L (á 5 pcs.) Finger tips M (á 5 pcs.) Finger tips S (á 5 pcs.)
Classification according to Medical Device Regulation (EU) 2017/745, Annex VIII	Class IIa according to Rule 9

Conformity Assessment	
Notified Body	Kiwa Dare B.V. Vijzelmolenlaan 7 3447 GX Woerden, The Netherlands
Identification Number	1912
Conformity Assessment Procedure according to	Medical Device Regulation (EU)2017/745, Annex IX
Certificate ID	22M00079CRT01
Expiry	16. April 2030

This Declaration of Conformity is issued under the sole responsibility of the manufacturer.
The products described above, as delivered, comply with the requirements of Regulation (EU) 2017/745 (MDR), the Regulation (EU) 2023/1230 (Machinery Regulation), the Directive 2014/53/EU (Radio Equipment Directive) and the Austrian Medical Devices Act BGBl. I No. 122/2021 as amended, as well as the above-mentioned applied standards.
This declaration is supported by the certification of the Quality Management System according to EN ISO 13485 by DQS Medizinprodukte GmbH. The products are provided with CE-marking.

CE 1912

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Graz, 16. Apr. 2025

Sabine Seereiner
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