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	(15703) TYMO®
UDI-DI	9120077180144
Intended Purpose	TYMO® is a monitoring and therapy device for the rehabilitation of patients suffering from motoric dysfunctions; it is primarily used for neurological rehabilitation purposes.
Basic UDI-DI	912007718TYMOF6
Including Software	TyroS Software Version 6.5.x
Components	TYMO Therapy Plate TYMO Rolling Element 1D TYMO Rolling Element 2D Multipad X Power Supply Bluetooth Adapter USB Extension
Classification according to Medical Device Regulation (EU) 2017/745, Annex VIII	Class I according to Rule 1 and 13

Conformity Assessment	
Conformity Assessment Procedure according to	Medical Device Regulation (EU) 2017/745, Annex IX, Chap. I
Certificate	This certificates is valid for devices manufactured in the manufacturing period given, only.
Valid for	12. Dec. 2024 - 05. Jan. 2028

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 Directive 2014/53/EU (Radio Equipment Directive), the regulation UK MDR 2022 and the Austrian Medical Devices Act BGBl. I No. 122/2021 as amended.
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 and UKCA marking.

CE

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Graz, 12. Dec. 2024