tyromotion

Declaration of Conformity

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

Product Specification	
Article Number and Product Name	(15726) PABLO®
UDI-DI	9120077180151
Intended Purpose	PABLO® is a modern therapy system for the rehabilitation of patients with motor dysfunctions and is basically used in neurological rehabilitation of the distal upper extremity.
Basic UDI-DI	912007718PABLO6J
Including Software	TyroS Software Version 6.5.x
Components	PABLO Handsensor 2x PABLO Motionsensor PABLO Multiboard PABLO Multiball PABLO Multipad L 2x PABLO Multipad S PABLO Charger PABLO Power Supply PABLO Strap Sets Bluetooth Adapter USB-Stick (TyroS) USB Extension
Classification according to Medical Device Regulation (EU) 2017/745, Annex VIII	Class I according to Rule1 and 13

Conformity Assessment	
Conformity Assessment Procedure according to Certificate	Medical Device Regulation (EU) 2017/745, Annex IX, Chap. I 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 2002 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