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	(11920) TYROSTATION
UDI-DI	9120077180038
Intended Purpose	The TYROSTATION has been developed as an accessory for the medical devices PABLO® and TYMO®.
Basic UDI-DI	912007718TYROSTATION4M
Including Software	TyroS Software Version 6.5.x
Components	TYROSTATION R2 Therapy Desk TYROSTATION R2 Chair
Classification according to Medical Device Regulation (EU) 2017/745, Annex VIII	Accessories to Class I according to Rule 1

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	19. Dec. 2024 - 03. 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, 19. Dec. 2024

Sabine Seereiner
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