EU Quality Management System Certificate

Medical Devices Regulation (EU) 2017/745 Annex IX
Chapter I and III (Class IIa, IIb and III Devices)

Certificate Number: M.2022.MDR.1005

Manufacturer Name	: BPR Swiss GmbH
Manufacturer Address	: Weststrasse 16, 3672 Oberdiessbach, Switzerland
Single registration number-SRN	: CH-MF-000018810
Authorised Representative Name ***(If applicable)***	: Managementsysteme Seiler, Klaus Seiler, SRN: DE-AR-000016462
Authorised Representative Address	: Managementsysteme Seiler Klaus Seiler Zum Saibling 3 D-88662 Überlingen / Bodensee Germany
Product Scope	: See the product list on the following page(s).

Based on the conformity assessment for the abovementioned manufacturer's quality management system in accordance with (EU) 2017/745 Medical Devices Regulation Annex IX Chapter I and Chapter III, UDEM Adriatic d.o.o. hereby declares that the requirements of Annex IX (Chapter I and Chapter III) of the Regulation (EU) 2017/745 have been met for the listed products in this certificate.
The manufacturer has established, documented and implemented a quality management system, which is subject to periodic surveillance assessments by UDEM Adriatic d.o.o. according to Annex IX Chapter I Section 3 of the aforementioned Regulation.
The report referenced below summarizes the result of assessments/examinations and includes reference to relevant CS, harmonized standards and test reports.
For Class III and Class IIb implantable devices referred to in the second subparagraph of Article 52(4) of Regulation (EU) 2017/745, covered by this certificate, an EU Technical Documentation Assessment Certificate is required before placing them on the market.

Report Number	: MDR.1055
Date of Issue	: 28/07/2022
Recertification Date	:
Reissue Date/No	:
Date of Expiry	: 27/07/2027

If any, Previous Certificate(s) No: NA

UDEM Adriatic d.o.o.
General Manager

UDEM Adriatic d.o.o. UDEM 2696

UDEM Adriatic d.o.o. is a Notified Body (identification no 2696) under (EU) 2017/745 Medical Devices Regulation.

Address: Radnička cesta 54/ R3 Zagreb– Croatia
E-Mail: info@udemadriatic.com **Web:** www.udemadriatic.com

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PRODUCT LIST COVERED BY THE CERTIFICATE

PRODUCT NAME	BASIC UDI-DI	RISK CLASS	EMDN CODE	MODEL	TYPE	INTENDED PURPOSE
Transportable dental treatment units	764018502 00001 LS	IIa	Z12110101	NA	DENTA-BOY 202,	The devices are transportable dental treatment units and serve for the general ambulant and stationary dental treatment
					DENTA-PORT 303,	
					DENTA-PRO,	
					COMBI-PORT PREMIUM	
					SMART-PORT	
					SMART-PORT PREMIUM	
					EASY-PORT 303	
					DENTA-CART 303/404	
					DENTA-CART CLINIC	
					COMBI-CART CLINIC,	
					P3-CART	
					DENTA-VAC	
					MINIMAX-VAC	
					MASTER-VAC	
					PRO-VAC,	
					SUPER-PORT	

Conditions for or limitations to the validity of this certificate : **NA**

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CERTIFICATE HISTORY		
Rev. No.	**Rev. Date**	**Description of Revision**
00	28/07/2022	Initial Certification