CMC Consumer Medical Care GmbH
Eichendorffstraße 12-14 | 89567 Sontheim/Brenz | Germany

Date 2022-03-22

EU Declaration of Conformity for Medical Devices Class I

We herewith declare that the following medical device

HARTMANN Stérilux Coton Pads
Reference Number: 918 480
Basic UDI-DI: 40424413707HF

of the product group

Group No.	Product Group	Class acc. to MDR (EU) 2017/745	Rule	UMDNS	EMDN	GMDN
1.01	**Medical Wadding**	I	1	15-216	M010101	58234

which was first placed on the market by CMC Consumer Medical Care GmbH, meets the applicable provisions, especially the general safety and performance requirements of the Regulation (EU) 2017/745 of the European Parliament and of the Council of 5. April 2017 on medical devices.

The Conformity Assessment Procedure according to Article 52 (7) of Regulation (EU) 2017/745 has been performed and the Technical Documentation according to Annexes II and III is kept available.

The EU Declaration of Conformity is issued under the sole responsibility of the CMC Consumer Medical Care GmbH (SRN: DE-MF-000006178).

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Dr. Benjamin Wenzel
Director R&D & RA

i.V.

Susanne Wolpert
Head of R&D & RA
Person Responsible for Regulatory Compliance acc. to Art. 15 MDR

This document is valid until: 2024-03-22

Annex: Applicable Standards

EN	1041		2013	Information supplied by the manufacturer of medical devices
EN ISO	14971		2019	Application of risk management to medical devices
EN ISO	13485		2016	Medical devices -- Quality management systems -- Requirements for regulatory purposes
EN ISO	15223	-1	2016	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements
EN	62366	-1	2015	Medical devices - Application of usability engineering to medical devices
EN ISO	10993	-1	2018	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
EN ISO	10993	-5	2009	Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity
EN ISO	10993	-10	2012	Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization
EN ISO	10993	-12	2012	Biological evaluation of medical devices - Part 12: Sample preparation and reference materials
Ph. Eur. 10.0, 2316	01/2008:0036		2008	Cotton, absorbent
Ph. Eur. 10.0, 4189	02/2008:0034		2008	Viscose Wadding, absorbent
Ph. Eur. 10.0, 201	07/2010:20612		2010	Microbiological evaluation of non-sterile products: Microbial enumeration test
Ph. Eur. 10.0, 205	04/2010:20613		2010	Microbiological evaluation of non-sterile products: Test for specifies micro-organisms
Ph. Eur. 10.0, 628	07/2017:50106		2017	Alternative methods for microbiological quality control
MEDDEV	2.7	Rev. 4	2016	CLINICAL EVALUATION: A GUIDE FOR MANUFACTURERS AND NOTIFIED BODIES UNDER DIRECTIVES 93/42/EEC and 90/385/EEC
MEDDEV	2.4/1	Rev. 9	2010	CLASSIFICATION OF MEDICAL DEVICES
MEDDEV	2.12-1	Rev. 8	2013	GUIDELINES ON A MEDICAL DEVICES VIGILANCE SYSTEM

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