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

Date 2022-06-03

EU Declaration of Conformity for Medical Devices Class I

We herewith declare that the following medical device

HARTMANN Watte 50 g
Reference Number: 110 122
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).

ppa.
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: 2024-06-03

Annex: Applicable Standards

EN ISO	20417		2021	Medical devices - Information to be supplied by the manufacturer*
EN ISO	14971		2019	Medical devices - Application of risk management to medical devices
EN ISO	13485		2016/A11: 2021	Medical devices -- Quality management systems -- Requirements for regulatory purposes
EN ISO	15223	-1	2021	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements
EN	62366	-1	2015+ AC:2015 + A1:2020	Medical devices - Application of usability engineering to medical devices*
EN ISO	10993	-1	2020	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	2013	Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization*
EN ISO	10993	-12	2021	Biological evaluation of medical devices - Part 12: Sample preparation and reference materials
EN ISO	10993	-18	2020	Biological evaluation of medical devices - Part 18: Chemical characterization of medical devices materials within a risk management process
ISO	10993	-23	2021	Biological evaluation of medical devices - Part 23: Tests for irritation
Ph. Eur. 10.8, Monograph No. 36	01/2008:0036 corrected 7.0		2008	Cotton, absorbent
Ph. Eur. 10.8, Monograph No. 36	01/2008:0034 corrected 6.0		2008	Viscose Wadding, absorbent
Ph. Eur. 10.8, Method No. 20612	01/2021:20612		2021	Microbiological evaluation of non-sterile products: Microbial enumeration test
Ph. Eur. 10.8, Method No. 20613	01/2021:20613		2021	Microbiological evaluation of non-sterile products: Test for specified micro-organisms
Ph. Eur. 10.8, Method No. 50106	07/2017:50106 corrected 10.0		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	2.12-1	Rev. 8	2013	GUIDELINES ON A MEDICAL DEVICES VIGILANCE SYSTEM

*non-harmonized standards. Although these standards are not yet harmonized, they represent the current state of the art and are appropriate to demonstrate compliance with Regulation (EU) 2017/745.

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