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

Date 2021-05-25

EC Declaration of Conformity for Medical Devices Class IIa

We herewith declare that the following medical device

HARTMANN cosmos Blasenpflaster
HARTMANN cosmos Plastry na pęcherze
HARTMANN cosmos Obliži za žulje
HARTMANN cosmos Flasteri za žuljeve
Article Number: 532 026/1
Basic UDI-DI: 40424413740HD

Group no.	Product group	Class acc. to 93/42/EEC	Rule	UMDNS	GMDN
3.01	**Hydrocolloids**	IIa	4 (3.)	10-288	43186

which are first placed on the market by CMC Consumer Medical Care GmbH, meet the applicable provisions, especially the essential requirements of the Council Directive 93/42/EEC of 14th June 1993.

The required conformity assessment procedure acc. to Annex II excluding (4) has been performed and the technical documentation is kept available.

The EC Declaration of Conformity is issued under the sole responsibility of the CMC Consumer Medical Care GmbH.

The conformity assessment procedure is under the supervision of the Notified Body:
MTIC InterCert S.r.l., Via G.Leopardi, 14, 20123 - Milano (MI), Italy, No. 0068.

ppa.

Dr. Benjamin Wenzel
Director R&D & RA

i.V.

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

This document is valid until: 2024-05-25

Annex 1: Applicable Standards

EN ISO 9001:2015	Quality management systems - Requirements
EN ISO 13485:2016 EN ISO 13485:2016/AC:2018	Medical devices - Quality management systems - Requirements for regulatory purposes
EN ISO 14971:2019	Medical devices - Application of risk management to medical devices
EN 62366-1:2015	Medical devices - Part 1: Application of usability engineering to medical devices
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 10993-10:2020	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
ISO 10993-18:2020	Biological evaluation of medical devices - Part 18: Chemical characterization of medical device materials within a risk management process
EN 13726-1:2002 EN 13726-1:2002/AC:2003	Test methods for primary wound dressings - Part 1: Aspects of absorbency
EN 13726-2:2002	Test methods for primary wound dressings - Part 2: Moisture vapor transmission rate of permeable film dressings
EN 1041:2008+A1:2013	Information supplied by the manufacturer of medical devices
DIN EN ISO 15223-1:2017	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements (ISO 15223-1:2012)
MEDDEV 2.7/1 rev. 4: 06.2016	Clinical evaluation: Guide for manufacturers and notified bodies
MEDDEV 2.12/1 rev. 8: 01.2013	Guidelines on a Medical Devices Vigilance System
EN 13726-3:2003	Non-active medical devices - Test methods for primary wound dressings - Part 3: Waterproofness
EN 13726-4:2003	Non-active medical devices - Test methods for primary wound dressings - Part 4: Conformability
ISO 11137-1: 2006/Amd.1:2013	Sterilization of health care products - Radiation - Requirements for development, validation and routine control of a sterilization process for medical devices.
ISO 11137-2: 2013	Sterilization of health care products - Radiation - Part 2: Establishing the sterilization dose.
ISO 11737-1: 2018	Sterilization of medical devices - Microbiological methods - Part 1: Determination of a population of microorganisms on products.
ISO 11737-2:2009	Sterilization of medical devices -- Microbiological methods -- Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process.
DIN EN 556-1: 2001/AC:2006	Sterilization of medical devices – Requirements for terminally sterilized medical devices to be labelled "Sterile" - Part 1: Requirements for terminally sterilized medical devices.
EN ISO 11607-1:2020	Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems
BS EN ISO 11607-2: 2017	Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes.
DIN EN ISO/IEC 17025:2018	General requirements for the competence of testing and calibration laboratories

CMC Consumer Medical Care GmbH

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VA TIN DE 814313953

CEO (Chairman of the Management Board)
Dr. Rainer Mangold

Date 2022-09-02

Annex 2: Extension of DoC

As the following product

HARTMANN cosmos	Blasenpflaster
HARTMANN cosmos	Plastry na pęcherze
HARTMANN cosmos	Obliži za žulje
HARTMANN cosmos	Flasteri za žuljeve

Article Number: 532 026/2

is identical to

HARTMANN cosmos	Blasenpflaster
HARTMANN cosmos	Plastry na pęcherze
HARTMANN cosmos	Obliži za žulje
HARTMANN cosmos	Flasteri za žuljeve

Article Number: 532 026/1

and no regulatory relevant changes have been made, the product falls under article 120 "Transitional provisions" of Regulation (EU) 2017/745.

Since the product is included in our certificate from our notified body MTIC InterCert S.r.l., which is valid until May 26, 2024, the product may continue to be placed on the market until that date in accordance with Article 120 (4) of Regulation (EU) 2017/745.

Therefore, we extend the validity of this Declaration of Conformity to cover the abovementioned product.

ppa.

Dr. Benjamin Wenzel
Director R&D & RA

i.A.

Veronika Fleck
Regulatory Affairs Manager

CMC Consumer Medical Care GmbH

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Date 2023-06-01

Annex 3: Supplement – EC Certificate Number

The CE Certificate Number is added as a supplement to the requested information regarding the Notified Body in this document as follows:

The conformity assessment procedure is under the supervision of the Notified Body:
MTIC InterCert S.r.l., Via G.Leopardi, 14, 20123 - Milano (MI), Italy, No. 0068,
Certificate No.: 0068/QCO-DM/186-2020

ppa.

Dr. Benjamin Wenzel
Director R&D & RA
Person Responsible for Regulatory
Compliance acc. to Art. 15 MDR

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Christina Baumeister
Head of Regulatory Affairs

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