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 medical devices of the following product groups

Group no.	Product group	Class acc. to 93/42/EEC	Rule	UMDNS	GMDN
3.01	**Hydrocolloids**	IIa	4 (3.)	10-288	43186
3.02	**Hydrogels**	IIa	4 (3.)	10-288	47764

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 & RA
Person Responsible for Regulatory Compliance acc. to Art. 15 MDR

This document is valid until: 2024-05-25

Sontheim/Brenz, 2024-05-22

Annex 2: Extension of validity

The medical devices of the following product groups

Group no.	Product group	Class acc. to 93/42/EEC	Rule	UMDNS	GMDN
3.01	**Hydrocolloids**	IIa	4 (3.)	10-288	43186
3.02	**Hydrogels**	IIa	4 (3.)	10-288	47764

fall under article 120 "Transitional provisions" of Regulation (EU) 2017/745, based on the Certificate No. 0068/QCO-DM/186-2020 according to Directive 93/42/EEC, which was issued by the notified body **MTIC InterCert S.r.l., ID-No. 0068**.

As the product groups mentioned above are covered by a written agreement for MDR application between CMC Consumer Medical Care GmbH and the notified body **Certiquality S.r.l., ID-No. 0546**, the products may continue to be placed on the market until the date December 31st, 2028, in accordance with Regulation (EU) 2023/607* amending Regulation (EU) 2017/745.

Therefore, we extend the validity of this Declaration of Conformity (originally dated on 2021-05-25 and formerly valid until May 25, 2024) to **December 31st, 2028**.

ppa.

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

i.V.

Christina Baumeister
Head of Regulatory Affairs

*Regulation (EU) 2023/607, Article 1, paragraph 1, letter b, point 3a (b)

CMC Consumer Medical Care GmbH

Mailing address
Eichendorffstraße 12-14
89567 Sontheim/Brenz, Deutschland

Phone +49 (73 25) 92 44 0
Fax +49 (73 25) 92 44 492

Head Office
Eichendorffstraße 12-14
89567 Sontheim/Brenz, Deutschland

Internet www.cmc-group.de
E-Mail info@cmc-group.de

District Court Ulm HRB 726 009

VA TIN DE 814313953

General Managers
Dr. Rainer Mangold, Holger Battling