

Declaration of Conformity

Manufacturers Name: CHEMENCE MEDICAL INC.

Manufacturers Address: 200 TECHNOLOGY DRIVE
ALPHARETTA, GA 30005
USA

SRN (Single Registration Number): US-MF-000000888

Certificate Number: MDR 755958

Authorized Representative Name (if applicable): ATLANTICO SYSTEMS LTD.

Authorized Representative Address (if applicable): 34 OLDFIELD,
KINGSTON, GALWAY,
REPUBLIC OF IRELAND

Basic UDI-DI: 854137001MPNKL

Name of the Device(s): Leukoplast® Skin Adhesive

Intended Purpose: Leukoplast® Skin Adhesive is for use by medical professionals for closing cuts or lacerations as well as small surgical incisions, including but not limited to catheter insertion locations, and punctures with easily adaptable wound edges. It is intended for topical application only.

Product code: 72541-04, 72541-05

Risk Classification: Class IIa Rule 4

Relevant Common Specifications: N/A

Notified Body name: BSI GROUP THE NETHERLANDS B.V.

Notified Body Address: SAY BUILDING, JOHN M. KEYNESPLEIN 9,
1066 EP AMSTERDAM NETHERLANDS

Notified Body Identification number: 2797

Conformity assessment route: CHEMENCE MEDICAL uses the following procedures for the CE-labeling of their products according to the Regulation MDR 2017/745:

Class IIa: EC conformity declaration according to Annex IX

This declaration of conformity is issued under the sole responsibility of CHEMENCE MEDICAL INC. We hereby declare that the medical device(s) specified above meet the provision of the Regulation (EU) MDR 2017/745 for medical devices. This declaration is supported by the Quality System approval to ISO 13485 certificate No. 97323 issued by BSI GROUP AMERICA, USA.

All supporting documentation is retained at the premises of the manufacturer.

This declaration of conformity shall be valid up to the time the CE certificate is no longer valid.

Signature:

Charnelle Thomas

NAME: Charnelle Thomas

FUNCTION: V.P. Regulatory

Place and date (dd.mm.yyyy) of issue:

17.04.2023

Attachment to declaration of conformity

Leukoplast® Skin Adhesive

Reference number	Description
72541-04	Leukoplast® Skin Adhesive, 0.7g (0.7ml)
72541-05	Leukoplast® Skin Adhesive, 0.36g (0.36ml)