

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):	exofin® Topical Adhesives
Intended Purpose:	exofin® is intended for topical application only to hold closed easily approximated skin edges of wounds from surgical incisions, including incisions from minimally invasive surgery, and simple, thoroughly cleansed, trauma-induced lacerations. exofin® may be used in conjunction with, but not in place of, deep dermal sutures. In vitro studies have shown that exofin® acts as a barrier to microbial penetration as long as the adhesive film remains intact. Clinical studies were not conducted to demonstrate microbial barrier properties. exofin® should be applied by trained medical or nursing staff.
Product code:	EX91011, EX91510, 10520010, 10520000
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 Regulation MDR 2017/745, Annex IX Chapter I and III

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This declaration of conformity shall be valid up to the time the CE certificate is no longer valid.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/Title/Place of Issue:

Date (dd.mm.yyyy) of issue:

Charnelle Thomas
.....

13 June 2023
.....

NAME: Charnelle Thomas
FUNCTION: V.P. Regulatory
200 Technology Dr.
Alpharetta, GA 30005

Attachment to declaration of conformity

exofin® High Viscosity Topical Adhesive

Reference number	Description
EX91011	exofin® High Viscosity Topical Adhesive, 1.0g (1.0ml)
EX91510	exofin® Micro, 0.5g (0.5ml)
10520010	Histoacryl Octyl , 1.0g (1.0ml)
10520000	Histoacryl Octyl Micro, 0.5g (0.5ml)