Declaration of Conformity

Manufacturer	CuraMedical B.V.
Address	Industrieweg 6B 1566 JP ASSENDELFT, The Netherlands
Product Type	Bone wax, Sterile, Non-Absorbable, Single Use
Classification (MDD, Annex IX)	IIb
GMDN code	46930
General intended use	CuraWax® non-absorbable Haemostatic Bone wax is used to control the bleeding of bone surfaces, acting by physical tamponade of the bone canals.
Brand name	CuraWax®

Types and Sizes:

CW-2.5g	2.5 gram; single piece
CW-012	2.5 gram; box of 12 pieces
CW-024	2.5 gram; box of 24 pieces

We herewith declare under our sole responsibility that the above-mentioned products meet the provisions of the following EC Council Directives and Standards. The design of the products and the Quality System meets the requirements according to Annex II – Section 3 and 4 of the Council Directive 93/42/EEC of June 14th, 1993 concerning medical devices. All supporting documentations are retained under the premises of the manufacturer and the notified body.

DIRECTIVES

General applicable directives:

Medical Device Directive: COUNCIL DIRECTIVE 93/42/EEC of June 14th, 1993 concerning medical devices (MDD 93/42/EEC), as last amended September 5th, 2007 (Directive 2007/47/EC).

Standards:

All relevant (Harmonized) Standards as published in the Official Journal of the European Communities and listed in the latest version of document: QS-1540-01 List of applicable standards CuraWax, are applicable to this type of product.

European Pharmacopoeia, Ph Eur Monographs **Beeswax and Isopropyl Palmitate**.

Notified Body	MDC Medical Device Certification GmbH, Kriegerstrasse 6, D-70191 Stuttgart, Germany Notified Body number: 0483		
Certificate no.	D1169400028	Expiry Date	2024-05-26
Date CE mark was first affixed	2020-04-30		
Place & Date	ASSENDELFT, 18-05-2020		
Signature			
Name	F. J. Hoogland		
Position	Director Marketing & Sales and Regulatory Affairs		

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Addendum:

Notified Body Confirmation letter D1169400035 was issued dated 24-04-2024 which confirms the grace period and extends our Certificates and Declarations of Conformity remain valid until 31 December 2027.