Declaration of Conformity

Manufacturer	CuraMedical B.V.
Address	Industrieweg 6B 1566 JP ASSENDELFT The Netherlands
Product Type	Oxidized Regenerated Cellulose Hemostat, Sterile, Absorbable, Single Use
Classification (MDD, Annex IX)	III
GMDN code	38771
Intended use	To be used in surgical procedures to control capillary, venous and small arterial bleeding when binding or other conventional methods of control are impractical or ineffective.
Brand name	**CuraCel® High Density**
Dye	Un-dyed (natural, beige-caramel)
Insulation / Coating	NA

Types and Sizes:

CH-603	26 x 26 mm	CH-607	50 x 75 mm	CH-660	152 x 230 mm
CH-604	26 x 76 mm	CH-637	76 x 102 mm		

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-1530-01 List of applicable standards Curacel, are applicable to this type of product.

United States Pharmacopoeia, USP Monographs **OXIDIZED REGENERATED CELLULOSE**.

Notified Body	MDC Medical Device Certification GmbH, Kriegerstrasse 6, D-70191 Stuttgart, Germany Notified Body number: 0483
Certificate no.	D1169400030 Expiry Date 2024-05-26
Date CE mark was first affixed	10-02-2010
Place & Date	ASSENDELFT, 02-02-2024
Signature	
Name	F. J. Hoogland
Position	Director Marketing & Sales and Regulatory Affairs

CURAMEDICAL BV QA APPROVED

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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.