



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 III
(MDD, Annex IX)
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® Fibrillar**

Dye Un-dyed (natural, beige-caramel)

Insulation / Coating NA

Types and Sizes:

CF-705 25 x 51 mm CF-738 102 x 102 mm

CF-710 51 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. D1169400018 Expiry Date 2023-01-09

Date CE mark was first affixed 10-02-2010

Place & Date ASSENDELFT, 25-06-2018

Signature

Name

F. J. Hoogland

Position

Director Marketing & Sales and Regulatory Affairs

