



Declaration of Conformity

Manufacturer CuraMedical B.V.
Address Industrieweg 6B
1566 JP ASSENDELFT, The Netherlands
Product Type Gelatin sponge with haemostatic effect, Sterile, Absorbable, Single Use
Classification III
(MDD, Annex IX)
GMDN code 48170
General intended use CuraSpon gelatin sponge is used during and after surgical procedures to achieve local haemostasis by tamponade effect.
Brand name **CuraSpon®**

Types and Sizes:

CS-010 Standard	80x50x10mm	CS-130 Sheet	80x50x3mm	CS-420 Dial 2-2	20x20x10mm
CS-011 Standard	70x50x10mm	CS-210 Tampon	80x ø 30mm	CS-430 Dial	30x30x10mm
CS-030 Streifen	80x40x10mm	CS-260 Powder	1g container	CS-442 Dial 4-2	40x10x10mm
CS-050 Size 16	80x20x10mm	CS-265 Powder	0.5g container	CS-452 Nasal tampon 5-2	50x10x10mm
CS-055 Strip	50x10x10mm	CS-275 Powder	1.5g container	CS-465 Strip	40x10x10mm
CS-060 Size 12-7	60x20x7mm	CS-310 Cube	10x10x10mm	CS-610 Size 100	125x80x10mm
CS-070 Size 13-5	51x13x10mm	CS-320 Cube XL	15x15x10mm	CS-650 Size 100c	125x80x1mm
CS-110 Special	80x50x1mm	CS-330 Dental 60	10x10x10mm	CS-710 Size 225	150x150x10mm
CS-111 Special	70x50x1mm	CS-410 Small	50x30x10mm	CS-950 Film	200x70x0.5mm

We herewith declare under our sole responsibility that the above-mentioned products meet the relevant 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-1511-01 List of applicable standards Curaspon, are applicable to this type of product.

Notified Body MDC Medical Device Certification GmbH,
Kriegerstrasse 6, D-70191 Stuttgart, Germany
Notified Body number: 0483
Certificate no. D1169400031 Expiry Date 2024-05-26
Date CE mark was first affixed 2007-05-07
Place & Date ASSENDELFT, 18-05-2021

Signature

Name F. J. Hoogland
Position Director Marketing & Sales and Regulatory Affairs

