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 (MDD, Annex IX)	III
GMDN code	48170
General intended use	CuraSpon gelatine 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

Reference to Technical File document: TF1520-01

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		

CURAMEDICAL BV QA APPROVED

Declaration of Conformity

Supplement of the Declaration of Conformity

FRM 423-01, Certificate no. D1169400031

Product category and certificate number	Product reference	Trade names	REF code	Size
Sterile haemostatic absorbable gelatine sponge and powder Certificate no. D1169400031	CuraSpon® Strip CS-465 40x10x10mm	Bloxang®	BL-465	40x10x10mm
		Gelaspon®	GE-465	40x10x10mm

CuraMedical B.V. hereby states that the supplement of the EU declaration of conformity FRM423-01 is issued under our sole responsibility because of the transition period of Medical Device Directive (MDD) to Medical Device Regulation (MDR), the devices are in accordance with Article 120 (3) of the Medical Device Regulation.

The products with new trade names Bloxang® and Gelaspon® are except of the trade name completely identical to Curaspon® from certificate no. D1169400031 and DoC nr FRM423-01 which were issued under conformity assessment procedure under the MDD before the MDR's Date of Application, and can be placed on the market until 26 May 2024.

CuraMedical B.V. hereby states that there are no significant changes in the design and intended purpose under MDR article 120 (3), the implementation is therefore allowed during the transitional period from MDD to MDR.

Place & Date ASSENDELFT, 08-03-2022

Signature

CURAMEDICAL BV QA APPROVED

Name F. J. Hoogland

Position Director Marketing & Sales and Regulatory Affairs