A completely absorbable haemostatic gelatin sponge consisting of purified neutral pharmaceutical gelatin foam of uniform porosity

General Characteristics

Gelatin Sponge produced from pharmaceutical gelatin Presentation in plates (standard), thin sheets (special and film), cylinder (tampon) and cubes (cube and dental)	Porcine Origin Possibility to impregnate with antibiotics or thrombin Does not stick to instruments Possibility to introduce in endoscopic procedures or trocar

Indications

All oozing bleedings which cannot be controlled by conventional techniques.	Provides haemostasis generally within 2 minutes after application Absorbable in maximum 3 days in contact with mucous tissue Absorbable in maximum 4 weeks when implanted in the organism

Packaging

Individually packaged in sterile blister.
Standard, Special, Tampon, Powder and Film double packaged and Cube single packaged.

Biocompatibility

In conformance with NEN ISO 10993-1

Manufacturer

CuraMedical B.V. – Industrieweg 6 – 1566 JP ASSENDELFT – The Netherlands – www.curamedical.com

Quality Management System - Scope: design, manufacturing and distribution of sterile absorbable hemostats

The MDC audit has proven that the Quality Management System meets all requirements for the standard EN ISO 13485 Medical Devices – Quality Management Systems – requirements for regulatory purposes (ISO 13485:2003).
Certificate N° 4091.48.01/01 of 7 May 2007 – Valid until 7 May 2012.

Quality System for design, manufacture and final inspection

The MDC audit has proven that the Quality System meets all requirements according to Annex II – section 3 of the council directive 93/42/EEC of 14 June 1993 concerning medical devices.
Certificate N° 4091.01.01/0 of 7 May 2007 – Valid until 7 May 2012. Surveillance in accordance with Annex II, section 5.

CE Marking : Class III according to Annex IX rules 8 and 17

The examination of design dossier of Curaspon by MDC has proven that according to the report of the file review No. E 4091.11/2007-05-07 the design meets the requirements according to Annex II – section 4 of the council directive 93/42/EEC of 14 June 1993 concerning medical devices. Certificate N° 4091.11.01/0 of 7 May 2007 – Valid until 7 May 2012.

Sterilization site

Isotron Netherlands BV - Ede – Netherlands, Certification EN ISO 13485 :2003 (BSI) et EN 552 :1994 Certificate N°MD 79613 Certification ISO 9001 :2000 (BSI) Certificate N° FM79617 and ISO 14001 Certificate N° 76904 by Kema B.V.

Method of sterilization

Gamma radiation

Shelf life

4 years

Available types				
Reference		**Dimensions (mm)**	**Thickness (mm)**	**Packaging per box**
CS-010	Curaspon® Standard	80 x 50	10	20 pieces
CS-110	Curaspon® Special	80 x 50	1	15 pieces
CS-210	Curaspon® Tampon	80	Ø 30	15 pieces
CS-260	Curaspon® Powder Paste Packaged in PE container (1 gram per container)	1 gram	NA	4 pieces
CS-310	Curaspon® Cube Packaged individually in Blister	10 x 10	10	50 pieces
CS-350	Curaspon® Cube Dental Packaged in PE container (30 pieces per container)	10 x 10	10	60 pieces
CS-950	Curaspon® Film	200 x 70	0,5	15 pieces

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