CuraCel® Standard Datasheet DCC-001.11 [2025-07-07]

A Sterile completely absorbable haemostatic gauze consisting of Oxidized Regenerated Cellulose (ORC) for Single use

General Characteristics

CuraCel® Standard is a sterile absorbable knitted fabric, prepared by the controlled oxidation of regenerated cellulose.

- Oxidized Regenerated Cellulose (ORC)
- Plant-based cellulose
- Haemostasis in 3 – 4 minutes
- Action mechanism independent from blood coagulation mechanism of the body
- Completely absorbed within 7 – 14 days
- Can be cut without fraying
- High flexibility and drapeability
- Does not stick or fall apart
- Storage conditions between 5 - 25°C.

Indications

CuraCel® Standard provides haemostasis in surgical procedures to control capillary, venous and small arterial bleeding when binding, suturing or other conventional methods of control are impractical or ineffective.

Provides haemostasis generally within 3 – 4 minutes after application.
When **CuraCel® Standard** Haemostat is used properly in minimal amounts, it is absorbed from the sites of implantation without tissue reaction. Absorption depends on; Haemostat amount used, tissue type and blood saturation degree. It should be saturated completely with blood to obtain the absorption effect. It is completely absorbed in 7 – 14 days.

Biocompatibility

In conformance with Harmonized Standard NEN ISO 10993-1

Packaging

Individually packaged. Primary packaging in medical paper envelope, sterile secondary packaging (sterile barrier) in aluminium foil

Method of sterilization

Gamma irradiation in accordance with Harmonized Standard EN ISO 11137-1

Shelf life

3 years

Manufacturer

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

Quality Management System - Scope: design, manufacturing and distribution of sterile absorbable haemostats – CE 0483

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 (EN ISO 13485:2016 + AC:2018 + A11:2021 – ISO 13485:2016). Certificate N° D1169400038 of May 29th 2024 – Valid until May 28th 2027.

Quality System for design, manufacture and final inspection – CE 0483

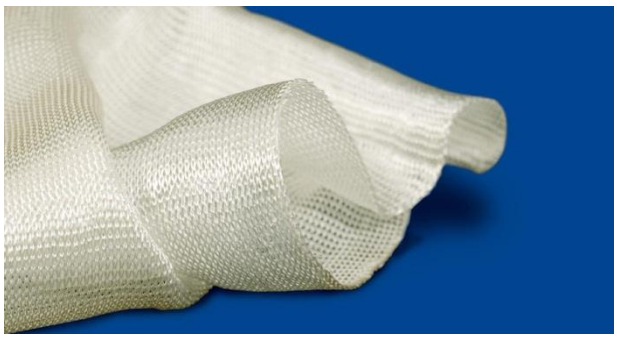
The MDC audit has proven that the Quality System meets all requirements according to Annex II – section 3 of the council directive 93/42/EEC of 14 June 1993 concerning medical devices.
Certificate N° D1169400028 of April 30th 2020 – Valid until May 26th 2024 . Surveillance in accordance with Annex II, section 5.
Notified Body Confirmation letter is issued D1169400035 dated 24-04-2024 that confirms the grace period and extends our certificates remaining valid until 31 December 2027.

CE Marking: Class III according to Annex IX rules 8 – CE 0483

The examination of the design dossier of CuraCel® by MDC has proven that according to report N° P20-01304-182806 of the file review 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° D1169400030 of May 18th 2021 – Valid until May 26th 2024.
Notified Body Confirmation letter is issued D1169400035 dated 24-04-2024 that confirms the grace period and extends our certificates remaining valid until 31 December 2027.

CuraCel® Standard Knit, is available in accordance with the following table.

CuraMedical Article no.	Description	Dimensions	Primary packaging	Secondary packaging	pcs per box
CC-501	Standard Knit	12,5 x 50 mm	Medical paper envelope	Aluminium foil	12
CC-507	Standard Knit	50 x 75 mm	Medical paper envelope	Aluminium foil	12
CC-535	Standard Knit	50 x 350 mm	Medical paper envelope	Aluminium foil	12
CC-537	Standard Knit	75 x 100 mm	Medical paper envelope	Aluminium foil	12
CC-540	Standard Knit	100 x 200 mm	Medical paper envelope	Aluminium foil	12



CuraCel® is also available in a High Density Knit (**CuraCel® High Density**: DCH-001) and a Fibrillose form (**CuraCel® Fibrillar**: DCF-001).

CuraCel® High Density

CuraCel® Fibrillar