

ELEKTROTECHNICKÝ ZKUŠEBNÍ ÚSTAV



ELECTROTECHNICAL TESTING INSTITUTE - CZECH REPUBLIC
ELEKTROTECHNISCHE PRÜFANSTALT - TSCHJECHISCHE REPUBLIK
INSTITUT ELECTROTECHNIQUE D'ESSAIS - RÉPUBLIQUE TCHÉQUE
ЭЛЕКТРОТЕХНИЧЕСКИЙ ИСПЫТАТЕЛЬНЫЙ ИНСТИТУТ - ЧЕШСКАЯ РЕСПУБЛИКА

Pod Lisem 129, 171 02 Praha 8 - Troja

CE Design Examination Certificate

No.: MED 080017

The Electrotechnical Testing Institute, Notified Body No. 1014, has performed examination of the design of the medical device

Oxidized Regenerated Cellulose Hemostat Sterile, Absorbable, Single use - class III - CURACEL®: models see enclosure No:1

according to Annex 2 section 4 of Governmental Order No. 336/2004 Coll. (Annex II section 4 of the Council Directive 93/42/EEC) incl. amendments

manufacturer **CuraMedical B.V.**
Industrieweg 6B -1566 JP, Assendelft, The Netherlands

and came to the conclusion that the medical device complies with provisions of Annex 2 section 3.2.3 of Governmental Order No. 336/2004 Coll. (Annex II section 3.2 (c) of the Council Directive 93/42/EEC) incl. amendments.

Details of the examination of the Design Dossier are presented in report No. 200863-02 of: 04.05.2012

In accordance with Art. 5 of Governmental Order No. 336/2004 Coll. (Art. 17 of Directive 93/42/EEC), incl. amendments the above specified medical device must be labelled CE 1014.

The manufacturer must inform the notified body about all changes in the approved medical device design which might effect the product's compliance with essential requirements of Governmental Order No. 336/2004 Coll. (Annex I of Directive 93/42/EEC), incl. amendments. In the event that the conditions under which the Certificate has been issued are violated, the notified body may suspend the Certificate's validity or cancel the Certificate.

Edition 2

Date of first issue of Certificate 21.3.2008 with validity until 31.5.2012
The validity of current Certificate is limited until: 28.5.2017

29.5.2012

Prague

Miroslav Sedláček
Certification and Inspection Manager



Stamp



200863-02

LIST OF MODELS

**Oxidized Regenerated Cellulose Hemostat Sterile, Absorbable,
Single use class III - CURACEL[®]:**

Ref. No.	Product dimension	Packaging
CC-501	5 x 1,25 cm	Boxes of 12 pieces
CC-503	2,5 x 2,5 cm	Boxes of 12 pieces
CC-505	2,5 x 5 cm	Boxes of 12 pieces
CC-507	5 x 7,5 cm	Boxes of 12 pieces
CC-535	5 x 35 cm	Boxes of 12 pieces
CC-537	7,5 x 10 cm	Boxes of 12 pieces
CC-540	10 x 20 cm	Boxes of 12 pieces
CC-560	15 x 23 cm	Boxes of 12 pieces

29.5.2012

