

# ELEKTROTECHNICKÝ ZKUŠEBNÍ ÚSTAV



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

Pod Lisem 129, 171 02 Praha 8 - Troja

## EC DESIGN-EXAMINATION CERTIFICATE

issued in accordance with Annex 2 of Government Order No. 336/2004 Coll.  
(Annex II of Directive 93/42/EEC)

No.: MED 100010

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

**Sterile haemostatic cotton based oxidized cellulose gauze - Curatamp®, class III, models see enclosure**

in accordance with Annex 2 clause 4 of Government Order No. 336/2004 Coll., which specifies technical requirements for medical devices (Annex II clause 4 of Directive 93/42/EEC) at

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

and states that the design of medical device meets the provisions of Government Order No. 336/2004 Coll. (Directive 93/42/EEC)

The details of the medical device design examination are presented in the audit report No. 401668-03 of: 11.07.2014.

The manufacturer must inform the notified body about any intention of substantial changes to the approved design of medical device which could affect the conformity with essential requirements in accordance with Annex 1 of Government Order No. 336/2004 Coll. (Annex 1 of Directive 93/42/EEC). In that case the conditions under which the certificate has been issued are violated, the notified body may suspend the validity of the certificate or cancel the certificate.

Edition 2

The first issue of this certificate from 10.2.2010 with validity until 31.8.2014

**The validity of this Certificate is limited until: 24.8.2019**

29.8.2014

Prague

Miroslav Sedláček  
Head of Certification Body



Stamp



401668-03

Sterile haemostatic cotton based oxidized cellulose gauze  
- Curatamp®, class III

Reference	Designation	Pcs per box
CT-101	50 x 12,5 mm	12
CT-103	25 x 25 mm	12
CT-105	50 x 25 mm	12
CT-107	50 x 75 mm	12
CT-135	50 x 350 mm	12
CT-137	75 x 100 mm	12
CT-138	100 x 100 mm	12
CT-140	100 x 200 mm	12



*Handwritten signature*