

# ELEKTROTECHNICKÝ ZKUŠEBNÍ ÚSTAV



ELECTROTECHNICAL TESTING INSTITUTE - CZECH REPUBLIC  
ELEKTROTECHNISCHE PRÜFANSTALT - TSCHHECHISCHE 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 100009

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

**Sterile heamostatic oxidized regenerated cellulose gauze - Curacel® High Density, 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. 401668-02 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 I 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



\* C E R / M E D 1 0 0 0 0 9 0 B L \*

401668-02

Sterile hemostatic oxidized regenerated cellulose gauze  
- Curacel® High Density, class III

Reference	Designation	Pcs per box
CH-603	26 x 26 mm	12
CH-607	50 x 75 mm	12
CH-637	76 x 102 mm	12
CH-660	152 x 230 mm	10



*[Handwritten signature]*