

EC CERTIFICATE

for the Quality Assurance System



according the directive 93/42/EEC,
Annex II excluding section (4)

As a notified body of the European Union, DEKRA Certification GmbH certifies, that the company
TYROLMED GmbH

Egger-Lienz-Straße 1d, 6020 Innsbruck, Austria

applies a quality assurance system for the medical devices listed in the annex according to the directive 93/42/EEC annex II. The approval is based on the result of the re-certification audit report no. 50021-Z5-00, the decision dated 2016-09-13 is only valid in connection with the successful performance of the annual surveillance audits.

This certificate is valid from 2016-10-01 to 2018-07-25

Certificate registration No.: 50021-16-03



Benannt durch/Designated by
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln und
Medizinprodukten
www.zlg.de
ZLG-BS-295.10.02

DEKRA Certification GmbH Stuttgart; 2016-09-13

Notified Body ID-number: 0124

DEKRA Certification GmbH * Handwerkstraße 15 * D-70565 Stuttgart * www.dekra-certification.de

Annex to the EC Certificate 50021-16-03 dated 2016-09-13

Revision status: 0

Date: 2016-10-01

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Devices/device categories included in the certificate

Class II b:

- MD 1104
 - Neutral electrodes for HF-surgery with and without cable