

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

Certified location:

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

applies a quality assurance system according to the Directive 93/42/EEC Annex II for the medical devices listed in the annex. The approval is based on the result of the re-certification audit report no. 50021-Z6-00, the decision dated 2018-07-20 and is only valid in connection with the successful performance of the annual surveillance audits.

This certificate is valid from 2018-07-26 to 2023-07-25

Registration No.: 50021-16-04



Ruth Delbeck-Bayer
DEKRA Certification GmbH Stuttgart; 2018-07-20
Notified Body ID-number: 0124



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

Annex to the EC Certificate No. 50021-16-04

Valid from 2018-07-26 to 2023-07-25

Revision status of the annex: 0 dated 2018-07-20

Devices/device categories included in the certificate:

Class II b:

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




Ruth Delbeck-Bayer



DEKRA Certification GmbH, Stuttgart, 2018-07-20
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