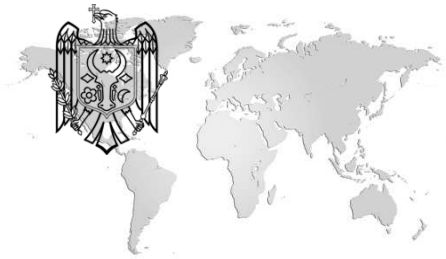
EC CERTIFICATE

for the Quality Assurance System

Digitally signed by Bolea Petru
Date: 2021.07.09 09:08:33 EEST
Reason: MoldSign Signature
Location: Moldova



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

QualiMed Innovative Medizinprodukte GmbH

Boschstraße 16, 21423 Winsen, Germany

Certified location:

Boschstraße 16, 21423 Winsen, Germany

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. 50289-Z7-00, the decision dated 2020-03-19 and is only valid in connection with the successful performance of the annual surveillance audits.
This certificate is only valid in connection with the main certificate no. 50289-16-07.

This certificate is valid from 2020-03-19 to 2024-05-26

Registration No.: 50289-16-07-1

DEKRA Certification GmbH • DEKRA Certification • D-70565 Stuttgart, Handwerkstraße 15

Ruth Delbeck-Bayer
DEKRA Certification GmbH Stuttgart; 2020-03-19
Notified Body ID-number: 0124

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

Annex to the EC Certificate No. 50289-16-07-1

Valid from 2020-03-19 to 2024-05-26

Revision status of the annex: 0 dated 2020-03-19

Devices/device categories included in the certificate:

Brand: Stron

Class II a:

- PYXIS-vq PTA Balloon Catheter
- GRAVIS PTA Balloon Catheter
- DELPHINUS PTA Balloon Catheter
- LATUS PTA Balloon Catheter
- FISTULEX PTA Balloon Catheter
- FISTULEX 0.035 PTA Balloon Catheter
- PYXIS-e PTA Balloon Catheter

Class II b:

- POLARIS Peripheral Vascular Self Expanding Stent System
- POLARIS-pp Peripheral Vascular Self Expanding Stent System
- PROPOS^{S} Peripheral Balloon Expandable Stent System
- PROPOSS^{6F} Peripheral Balloon Expandable Stent System
- PROPOSX^{S} Peripheral Balloon Expandable Stent System

Class III:

- VMAX Aspiration Catheter
- GALAXY Rapamycin-Eluting Coronary Stent System
- PYXIS-c PTCA Balloon Catheter

For the placing on the market of class III devices covered by this certificate an EC design-examination certificate according to directive 93/42/EEC annex II (4) is required.

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