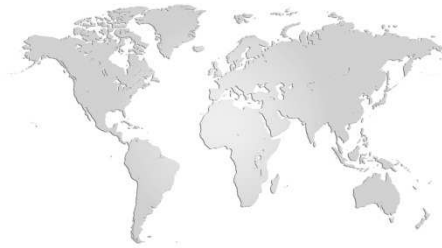


# EC CERTIFICATE

## 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  
**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.: 50289-16-07-3




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](http://www.zlg.de)  
**ZLG-BS-295.10.02**

# Annex to the EC Certificate No. 50289-16-07-3

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: IK**

### Class II a:

- PERSEUS-q PTA Balloon Catheter
- PERSEUS-e PTA Balloon Catheter

### Class II b:

- PONTOS Peripheral Vascular Self Expanding Stent System
- PONTOS-pp Peripheral Vascular Self Expanding Stent System
- TALON<sup>Minor</sup> Peripheral Balloon Expandable Stent System
- TALON<sup>Minor 6F</sup> Peripheral Balloon Expandable Stent System
- TALON<sup>Minor</sup>- Peripheral Balloon Expandable Stent System

### Class III:

- POLLUX Aspiration Catheter
- ABARIS Rapamycin-Eluting Coronary Stent System
- PEGASUS 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.



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

DEKRA Certification GmbH \* Handwerkstraße 15 \* D-70565 Stuttgart \* [www.dekra-certification.de](http://www.dekra-certification.de)