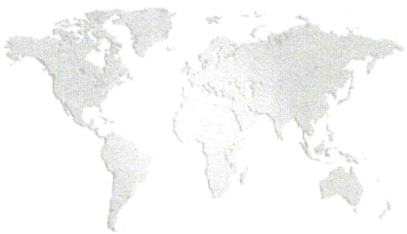
EC CERTIFICATE

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

Occlutech GmbH

Winzerlaer Straße 2, 07745 Jena, Germany

Certified location:

Winzerlaer Straße 2, 07745 Jena, 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. 51030-Z4-00, the decision dated 2020-02-12 and is only valid in connection with the successful performance of the annual surveillance audits.

This certificate is valid from 2020-02-15 to 2024-05-26

Registration No.: 51030-16-04

DEKRA Certification GmbH D-70565 Stuttgart, Handwerkstraße 15

Ruth Delbeck-Bayer
DEKRA Certification GmbH Stuttgart; 2020-02-12
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. 51030-16-04

Valid from 2020-02-15 to 2024-05-26

Revision status of the annex: 0 dated 2020-02-15

Devices/device categories included in the certificate:

Class I s:

For the products listed below, review of the Quality Assurance System refers exclusively to aspects of manufacture concerned with securing and maintaining sterile conditions.

- Occlutech® Loader

Class III:

- Figulla® Flex II ASD
- Figulla® Flex II PFO
- Figulla® Flex II UNI
- Occlutech® Occlusions-Pusher
- Occlutech® Sizing Balloon
- Occlutech® Delivery Set

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.

DEKRA Certification GmbH D-70565 Stuttgart, Handwerkstraße 15

Ruth Delbeck-Bayer
DEKRA Certification GmbH, Stuttgart, 2020-02-12
Notified Body ID-number: 0124