



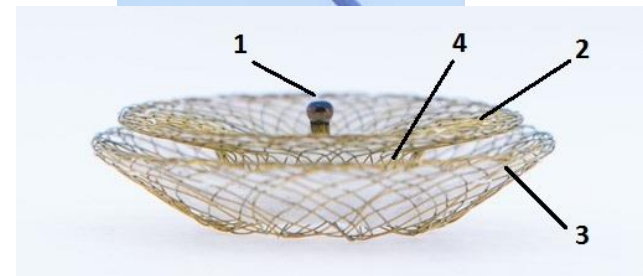
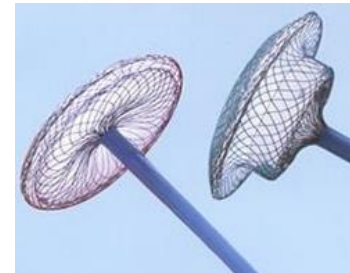
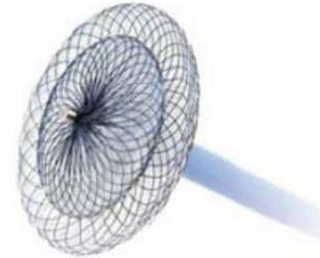
Questmed Skills / Expertise

2021-06-18

Dr. Christian Abicht

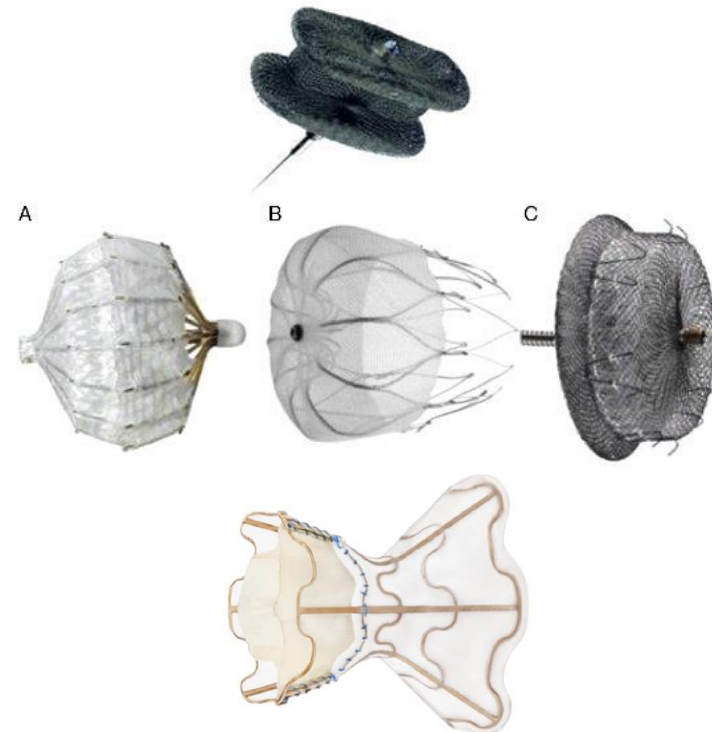
Type of Cardiovascular Occluders

- PFO MemoPart™, Lepu Medical Technology
- ASD Yatai Scientific CO.LTD
- ASD Occlutec GmbH
- PDA Yatai Scientific CO.LTD



Type of Cardiovascular Occluders

- VSD Yatai Scientific CO.LTD
- PVL Amplatzer Vascular Plug III
- LAA PLAATO, Watchman, Cardiac Plug
- AFR V-Wave Occluder V-Wave Ltd



- **occlude undesired blood flow,**
- device embolization,
- pericardial effusion,
- unstable device placement,
- structural and functional integrity during the expected lifetime of the device,
- minimize haemolysis,
- undesired thrombus formation, device-related thrombus,
- biocompatibility,
- resist corrosion,
- particulate generation,
- ...

Accreditation Cardiac

Questmed Accreditation

- **ISO/DIS 22679:** Cardiac occluders
- Occluder: Durability under axial and hydrodynamic load
AW-16
Co-applicable:
DIN EN ISO 25539-1
DIN EN ISO 25539-2
- Axial load
- Hydrodynamic load
- **ASTM F3306:** Standard Test Method for Ion Release
Evaluation of Medical Implants



Deutsche Akkreditierungsstelle GmbH

Entrusted according to Section 8 subsection 1 AkkStelleGG in connection with Section 3 subsection 1 AkkStelleGG
Signatory to the Multilateral Agreements of EA, ILAC and IAF for Mutual Recognition

Accreditation



The Deutsche Akkreditierungsstelle GmbH attests that the testing laboratory

Questmed GmbH
at the sites
Albert-Einstein-Ring 9, 14532 Kleinmachnow
Ilmstraße 18, 07743 Jena

is competent under the terms of DIN EN ISO/IEC 17025:2018 and in accordance to carry out tests in the following field:

Field: Medical devices and the Directive 93/42/EEC

Testing fields/test items: Physical and physical-chemical testing of non-active implants

The accreditation certificate shall only apply in connection with the notice of accreditation of DAkkS 2020 with the accreditation number D-PL-18753-02. It comprises the cover sheet, the reverse side of the cover sheet and the following annex with a total of 7 pages.

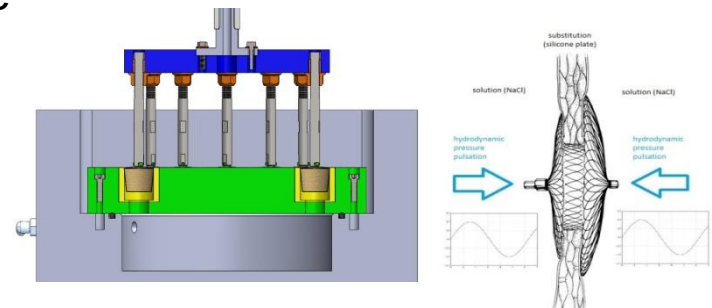
Registration number of the certificate: **D-PL-18753-02-00**

Frankfurt am Main,
04.03.2020

Dipl.-Biol. Uwe Zimmermann
Head of Division

Transition issued:
20.03.2020

The certificate together with its annex reflects the status at the time of the date of issue. The current status of the scope of accreditation can be found in the database of accredited bodies of Deutsche Akkreditierungsstelle GmbH.
<http://www.dakks.de/en/akkred/operational-bodies.html>
This document is a translation. The definitive version is the original German accreditation certificate.
DAkkS 2020



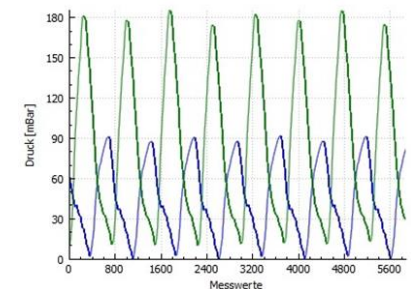
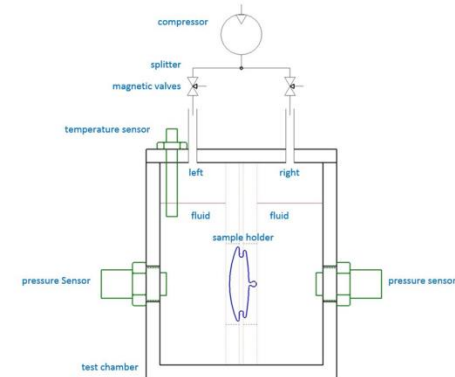
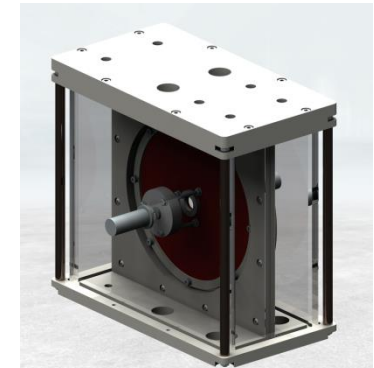
ISO Working Group

- Standard for Cardiac occluders
- ISO/TC 150/SC 02/WG 08 "Cardiac occluders"
- ISO/DIS 22679 (2021-05-13)
- full requirements for occluder development
- Members active US, China, UK, Germany
- US: Gore, Abbot, BSC, BDC, Medtronic
- China: Lifetech
- Germany

Type	Differential Pressure pulsation [mmHg]
PFO, ASD	14
PDA	110
VSD	110
PVL	119
AFR	30
LAA	18
LAA(pAF)	27
AAA	20

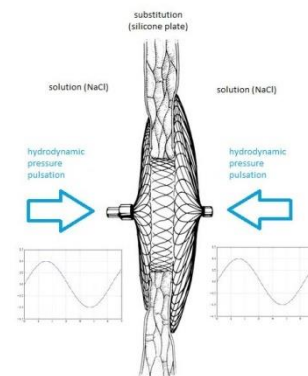
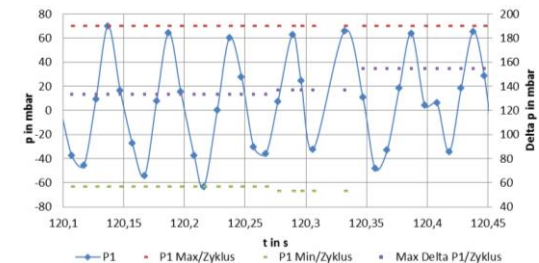
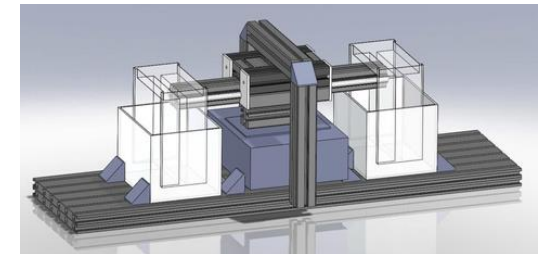
Physiological durability stress cardiovascular implants

- 400 Million cycles
- Testing up to **30 implants** per test system
- Dynamic pressure pulsation from 10 mmHg to 220 mmHg
- Fluid flow external 0.5 l/min to 15 l/min
- Test medium Ringer's solution, 37 °C
- Test frequency 1.2 Hz up to **90 Hz**
- Datarate measuring 10kHz
- **ISO/DIS 22679**



Physiological durability stress cardiovascular implants

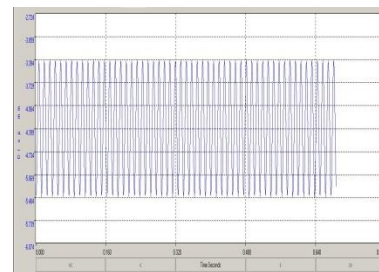
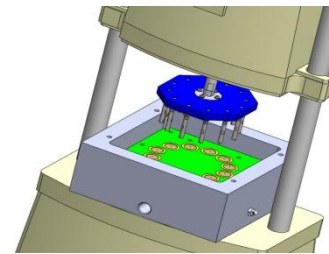
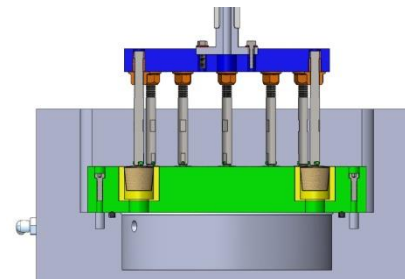
- 10 Million cycles (usually)
- Dynamic pressure pulsation from 5 mmHg to 200 mmHg
- Dynamic translation 3 mm
- Fluid flow external 0.5 l/min to 15 l/min
- Test medium Ringer's solution, 37 °C
- Test frequency 4 Hz up to 21 Hz
- Testing 4 to 6 implants per test system
- **ISO/DIS 22679**



Test system Axial Motion

Durability stress cardiovascular implants

- 400 Million cycles
- Dynamic translation up to 10 mm
- Fluid flow
- Test medium Ringer's solution, 37 °C
- Test frequency 1.2 Hz up to 80 Hz
- Testing 12 implants per test system
- **ISO/DIS 22679**



Testing of Implants



Accreditation according ISO 17025 and 93/42/EEC since 2009

Class III (93/42/EEC, MDR)

- Fatigue Cardiovascular Implants
- Wear Knee, Shoulder, Ankle
- Fatigue Knee, Hip, Shoulder, Spine

Class II (93/42/EEC, MDR)

- Fatigue Dental Implantat
- Fatigue Osteosynthesis (bone plates)
- Static tests

Location Kleinmachnow and Jena accredited

Member of **Standardization** Organization Groups

- DIN Cardiovascular, Dental
- ISO/DIS 22679 Cardiac occluders
- ISO 25539
- ASTM WK61103, F3306





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