

Germany, 26.03.2021

Berger Surgical Medical Products GmbH • take-off-Gewerbepark 4 • D-78579 Neuhausen ob Eck

To: Vietnamese Ministry of Health (Department of Medical Equipment and Construction)

Dear Ladies and gentlemen,

Please find attached our certificate to our Quality Management System, registration number D1031900024, issued by our Notified Body MDC (Medical Device Certification GmbH) Kriegerstraße 6. D-70191 Stuttgart, Germany, for registration purposes.

Legitimate representative of legal product owner

Tuttlingen, 26.03.2021

Thilo Henzler
CEO

BS Berger Surgical
Medical Products GmbH
take-off-Gewerbepark 4
D-78579 Neuhausen ob Eck
www.berger-surgical.de



**Industrie- und Handelskammer
Schwarzwald - Baar - Heuberg**
Wir bescheinigen die Vorlage der
Erklärung. Hinsichtlich des Inhalts
ist nichts Gegenteiliges bekannt.
78050 Villingen-Schwenningen,

den 26. MRZ. 2021

Winker-Jerkovle



EC Certificate

mdc medical device certification GmbH

Notified Body 0483
herewith certifies that

Berger Surgical Medical Products GmbH
Take-off Gewerbepark 4
78579 Neuhausen ob Eck
Germany

for the scope

Suction instruments and self-retaining retractors

has introduced and applies a

Quality System

for the design, manufacture and final inspection.

The mdc audit has proven that this quality system
meets all requirements according to

Annex II – excluding Section 4
of the Council Directive 93/42/EEC

of 14 June 1993 concerning medical devices.

The surveillance will be held as specified in Annex II, Section 5.

| | |
|------------------|------------------|
| Valid from | 2020-11-26 |
| Valid until | 2024-05-26 |
| Registration no. | D1031900024 |
| Report no. | P20-01039-179501 |
| Stuttgart | 2020-11-26 |




Head of Certification Body



mdc medical device certification GmbH
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TỔNG LÃNH SỰ QUÁN NƯỚC CHXHCN VIỆT NAM
tại Frankfurt am Main, CHLB Đức

1. Quốc gia: **Việt Nam**
Country:
- Giấy tờ, tài liệu này**
This public document
2. do Ông (Bà): **Winker-Jerkovic** ký
has been signed by:
3. với chức danh: **Cán bộ phụ trách**
acting in the capacity of:
4. và con dấu của: **Phòng Công nghiệp và Thương mại**
bears the seal/stamp of: vùng Schwarzwald-Baar-Heuberg
được chứng nhận / hợp pháp hóa lãnh sự
Certified
5. tại: **Frankfurt** 6. ngày: **07/04/2021**
at: the:
7. Cơ quan cấp: **Tổng lãnh sự quán Việt Nam tại Frankfurt/Main**
by
8. Số: **616/2021/CN-HPHLS**
No:

Lãnh sự/ Consul



Nguyễn Hà Linh

