

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 System, registration number D1031900023, 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-Jerkovits

Certificate

mdc medical device certification GmbH
certifies that



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

for the scope

**development, manufacturing, distribution and repair of
surgical instruments**
**service process in the area of marking and cleaning of
surgical instruments**

has introduced and applies a

Quality Management System

The mdc audit has proven that this quality management system
meets all requirements of the following standard

EN ISO 13485

Medical devices – Quality management systems –
Requirements for regulatory purposes

EN ISO 13485:2016 + AC:2016 - ISO 13485:2016

Valid from	2020-11-06
Valid until	2023-06-20
Registration no.	D1031900023
Report no.	P20-00340-170704
Stuttgart	2020-11-06


Head of Certification Body



mdc medical device certification GmbH
Kriegerstraße 6
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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: **617/2021/CN-HPHLS**
No:

Lãnh sự/ Consul



Nguyễn Hà Linh