

EC Certificate

mdc medical device certification GmbH

Notified Body 0483
herewith certifies that

**AMET OOD
bvld. Europe 177
1331 Sofia
Bulgaria**

for the scope

**HF-surgical devices
(see attachment)**

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	2021-02-08
Valid until	2024-05-26
Registration no.	D1282100015
Report no.	P19-00835-149552
Stuttgart	2021-02-08



Head of Certification Body



Benannt durch/Designated by
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln und
Medizinprodukten
www.zlg.de
ZLG-BS-246.10.06

Attachment of the certificate

No. D1282100015

Date 2021-02-08

Page 1 of 1

Product category	Product	Class
HF-surgical devices	AMETOM 200 HBS200i AMETOM 300 HBS300i AMETOM 820 HBS300, HBS100 HBS100 Varex	IIb



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