



CERTIFICATE

EC Certificate No. 1434-MDD-336/2021
EC Design-examination
Directive 93/42/EEC concerning medical devices

Polish Centre for Testing and Certification certifies
that the documentation submitted by:

amg International GmbH

Boschstrasse 16, 21423 Winsen-Luhe, Germany

related to the medical device, class III

UNITY-B

Biodegradable Balloon Expandable Biliary Stent System

The list of medical devices covered by this certificate is provided in the annexes 1-3

was examined in accordance with Annex II (Section 4) to Directive 93/42/EEC (as amended) implemented into
Polish law, as evidenced by the audit conducted by the PCBC

Validity of the Certificate: from 20.05.2021 to 27.05.2024

The date of issue of the Certificate: 20.05.2021



Issued under the Contract No. MD-52/2016

Application No: 141/2016, 188/2021

Certificate bears the qualified signature.

Warsaw, 20/05/2021

Module H1

FBM-24-E_10

Vice-President



ANNEX 2 TO THE CERTIFICATE

VALID ONLY WITH CERTIFICATE

No 1434-MDD-336/2021

List of medical devices covered by the certificate:

UNITY-B Endoscopic Biodegradable Balloon Expandable Biliary Stent System Brand: amg

Intended Use

The UNITY-B Endoscopic Biodegradable Balloon Expandable Biliary Stent System is used to drain obstructed bile ducts.

Technical data

Stent material	MgMnNd21
Stent coating	PLGA (Poly(L-lactide-co-glycolide))
Stent diameter	8.0 / 9.0 /10.0 mm
Stent length	57 mm
Usable Catheter Length	190 cm
Approach	Endoscopic
Recommended Guidewire Compatibility	0.035"
Sterilization Method	ETO gas
Catalogue numbers	19 MBXb 08057A 19 MBXb 09057A 19 MBXb 10057A



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Vice-President