



# CERTIFICATE

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**EC Certificate No. 1434-MDD-335/2021**  
**Full Quality Assurance System**  
**Directive 93/42/EEC concerning medical devices**

Polish Centre for Testing and Certification certifies  
that the quality assurance system in the organization:

**amg International GmbH**

**Boschstrasse 16, 21423 Winsen-Luhe, Germany**

for the design, manufacture and final inspection of  
medical devices, 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 to EC Design-examination Certificate No. 1434-MDD-336/2021*

complies with requirements  
of Annex II (excluding 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 H2/3/4/5  
FBM-26-E\_9

**Vice-President**