

EC Declaration of Conformity

We declare under our sole responsibility that the medical device

| Description | Type | Catalogue Number |
|--|-------------------------------|---|
| Biodegradable Balloon- expandable Biliary Stent System | UNITY-B Endoscopic | 19 MBXb 08057A 19 MBXb 09057A 19 MBXb 10057A |
| Explanations: uu = usable catheter length [cm] dd = balloon diameter [mm] ll = length of stent [mm] A = guidewire compatibility ["] | | Range: uu: 190 cm dd: 8.00 to 10.00 mm ll: 57 mm A: 0.035" |

| Class | Annex of the Directive | Rule |
|-------|------------------------|------|
| III | IX | 8.3 |

meets all the provisions of the Directive 93/42/EEC which apply to it.

| | |
|--|-------------------|
| Conformity Assessment Procedure | Annex II.4 |
|--|-------------------|


| Certificate Number | Valid until |
|--------------------|-------------|
| 1434-MDD-335/2021 | 27.05.2024 |
| 1434-MDD-336/2021 | 27.05.2024 |

| EN ISO 13485:2016 | Valid until |
|----------------------|-------------|
| 50563-14-01 (CE0124) | 09.12.2024 |

| GMDN Code | UMDNS Code |
|-----------|------------|
| 65682 | 17-672 |

| | | |
|---|----------------|--|
| Identification Code of the Notified Body | CE 1434 | PCBC S.A. 469 Puławska Street 02-844 Warsaw Poland |
|---|----------------|--|

Winsen-Luhe, 17.11.2021

Signature: 
 Name (printed): Andrea Elferink
 Position: Head of Quality Management
 & Regulatory Affairs

amginternational
A Q3 Medical Company

Manufacturer:
 amg International GmbH
 Boschstraße 16, 214123 Winsen-Luhe
 Germany

This declaration of conformity is valid until: 27.05.2024

Datei/File: DOC UNITY-B Endo_211117

AFB033_16B Declaration of Conformity GI, Effective date: 09.03.2020