

EC DECLARATION OF CONFORMITY

Manufacturers Name: **Andramed GmbH**

Manufacturers Address: Schießwieslenstraße 18
D-72766 Reutlingen
Germany

Name of Device(s) : Retrieval Devices
(AndraSnare, AndraSnare Micro, AndraBasket,
Loopmaster- Sochman Snare)

Device Order Codes : see Annex 1

Classification : Class IIa due to Rule 6 Annex 9, 93/42/EEC

Conformity Assesment Route : Annex II excluding Section 4, directive 93/42/EEC

EC Desing Examination Certificate No. G1 005176 0002 Rev.01
valid till: 26-05-2024

Notified Body : TÜV Süd Product GmbH
Ridlerstr. 65
80339 München
Kenn-Nr. / Ident-No: 0123

We hereby declare that the medical device(s) specified above meet the provisions of the Council Directive No. 93/42/EEC for Medical Devices. This declaration is supported by the Quality System approval DIN EN ISO 13485:2016. All supporting documentation is retained at the premises of the manufacturer.

Reutlingen, Date (20/11/2019)


Jessica Seifert
CEO Andramed GmbH
Medical Devices

Andramed GmbH • Schießwieslenstr. 18 • D-72766 Reutlingen

Annex 1

Product Description	Order Code
Andra-Snare / Fangschlinge 5mm	AS-5
Andra-Snare / Fangschlinge 10mm	AS-10
Andra-Snare / Fangschlinge 15mm	AS-15
Andra-Snare / Fangschlinge 20mm	AS-20
Andra-Snare / Fangschlinge 25mm	AS-25
Andra-Snare / Fangschlinge 25mm / 65 cm	AS-25/65
Andra-Snare / Fangschlinge 25mm / 150 cm	AS-25/150
Andra-Snare / Fangschlinge 30mm	AS-30
Andra-Snare / Fangschlinge 35mm	AS-35
Andra-Snare / Fangschlinge Micro 2mm	ASM-2
Andra-Snare / Fangschlinge Micro 4mm	ASM-4
Andra-Snare / Fangschlinge Micro 7mm	ASM-7
Introducer Sheath 4F 110cm	INT4F-110
Loopmaster-Sochman-Snare	ASL-25
AndraBasket ABT-H-4-2.5-12-090H	ABT-H-4-2.5-12-090H
AndraBasket ABT-H-4-2.5-12-120H	ABT-H-4-2.5-12-120H
AndraBasket ABT-H-4-3-15-090H	ABT-H-4-3-15-090H
AndraBasket ABT-H-4-4-17-090H	ABT-H-4-4-17-090H
AndraBasket ABT-H-4-2-12-090H	ABT-H-4-2-12-090H
AndraBasket ABT-H-4-2-12-120H	ABT-H-4-2-12-120H
AndraBasket ABT-H-4-3-15-120H	ABT-H-4-3-15-120H
AndraBasket ABT-H-4-4-17-120H	ABT-H-4-4-17-120H
AndraBasket ABT-H-4-12-090H	ABT-H-4-12-090H
AndraBasket Gastro ABT-G-4-5-25-215H	ABT-G-4-5-25-215H
AndraBasket Gastro ABT-G-4-5-30-215H	ABT-G-4-5-30-215H
AndraBasket Gastro ABT-G-4-7-25-215H	ABT-G-4-7-25-215H
AndraBasket Gastro ABT-G-4-7-30-215H	ABT-G-4-7-30-215H