

Hersteller / *Manufacturer:* **AS Medizintechnik GmbH**

Anschrift / *Address:* **Sattlerstr. 15
78532 Tuttlingen / Germany**

SRN-Nummer / *SRN-No.:* DE-MF-000005601

Produktgruppe/ *Product group:* **Dilatator / Dilators**

Artikel / *Articles:* Siehe Anhang / *see annex*

Basis-UDI-DI / *Basic UDI-DI:* 4050123-34-0420-HY

Risikoklasse / *Risk class:* Klasse Ir / *Class Ir*

Regel / *Rule:* 6

UMDNS: 15215 Dilator, sonstige/ *Dilators, Other*

GMDN: 11260 Nasal dilator

EMDN: C9002 Vascular and fascial dilators

Zweckbestimmung / *Intended use:* Instrument zum Weiten und Dehnen bestehender Körperöffnungen (z.B. Gefäße, Tränenkanal, Harnröhre.)
Instrument for widening and stretching existing body openings (e.g. vessels, tear duct, urethra.)

Zertifikat / *Certificate:* D1085600030

Mit der vorliegenden Konformitätserklärung erklären wir in alleiniger Verantwortung, dass das oben aufgeführte Medizinprodukt die grundlegenden Sicherheits- und Leistungsanforderungen gemäß Anhang I der Verordnung (EU) 2017/745 erfüllt.

With the present Declaration of Conformity, we hereby declare under our sole responsibility, that the above-mentioned medical device meets the essential safety- and performance requirements, defined in annex I of the Regulation (EU) 2017/745.

Das Konformitätsbewertungsverfahren wurde durchgeführt nach Anh. IX Kapitel I und III der Verordnung (EU) 2017/745 für Medizinprodukte.

The Conformity Assessment Procedure has been performed according to annex IX, Chapter I and III of the Regulation (EU) 2017/745 for medical devices.

Angewandte Spezifikationen für die die Konformität erklärt wird sind im FB 4.2.3.1 Liste Normen, Verordnungen und Gesetze aufgeführt.

Applied specifications for which conformity is declared are listed in FB 4.2.3.1 List of standards, regulations and laws.

Diese Erklärung verliert sofort ihre Gültigkeit in Folge jeder, nicht durch uns schriftlich autorisierten Änderung oder Reparatur am Produkt.

This declaration becomes invalid immediately, when repairs or alterations occur to the product, without prior written approval by us.

Benannte Stelle: Kennnummer: 0483
 mdc medical device certification GmbH,
 Kriegerstr. 6, 70191 Stuttgart

Notified Body: Identification number: 0483
 mdc medical device certification GmbH,
 Kriegerstr. 6, 70191 Stuttgart

Diese Erklärung ist gültig bis zum 19.07.2027
 this declaration is valid until: 19.07.2027



Tuttlingen, den 05.09.2023

Nino Schilling
 Geschäftsleitung / Managing Director

Anhang / Annex

Artikel-Nr. / Item number	Artikelbezeichnung deutsch	Articel description
27-561-02	Ritter Stirnhöhlen-Dilatator, Ø 2,5 mm,16 cm	Ritter Frontal Sinus Bougie, Ø 2,5 mm,16 cm
27-561-03	Ritter Stirnhöhlen-Dilatator, Ø 3,0 mm,16 cm	Ritter Frontal Sinus Bougie, Ø 3,0 mm,16 cm
27-561-04	Ritter Stirnhöhlen-Dilatator, Ø 4,0 mm,16 cm	Ritter Frontal Sinus Bougie, Ø 4,0 mm,16 cm
27-561-05	Ritter Stirnhöhlen-Dilatator, Ø 5,0 mm,16 cm	Ritter Frontal Sinus Bougie, Ø 5,0 mm,16 cm
31-015-05	Cooley Gefäß-Dilatator, Ø 0,5 mm, 13 cm	Cooley Vascular Dilator, Ø 0,5 mm, 13 cm
31-015-10	Cooley Gefäß-Dilatator, Ø 1,0 mm, 13 cm	Cooley Vascular Dilator, Ø 1,0 mm, 13 cm
31-015-15	Cooley Gefäß-Dilatator, Ø 1,5 mm, 13 cm	Cooley Vascular Dilator, Ø 1,5 mm, 13 cm
31-015-20	Cooley Gefäß-Dilatator, Ø 2,0 mm, 13 cm	Cooley Vascular Dilator, Ø 2,0 mm, 13 cm
31-015-25	Cooley Gefäß-Dilatator, Ø 2,5 mm, 13 cm	Cooley Vascular Dilator, Ø 2,5 mm, 13 cm
31-015-30	Cooley Gefäß-Dilatator, Ø 3,0 mm, 13 cm	Cooley Vascular Dilator, Ø 3,0 mm, 13 cm
31-015-40	Cooley Gefäß-Dilatator, Ø 4,0 mm, 13 cm	Cooley Vascular Dilator, Ø 4,0 mm, 13 cm
31-015-50	Cooley Gefäß-Dilatator, Ø 5,0 mm, 13 cm	Cooley Vascular Dilator, Ø 5,0 mm, 13 cm
31-016-05	Cooley Gefäß-Dilatator, Ø 0,5 mm, 15 cm	Cooley Vascular Dilator, Ø 0,5 mm, 15 cm
31-016-10	Cooley Gefäß-Dilatator, Ø 1,0 mm, 15 cm	Cooley Vascular Dilator, Ø 1,0 mm, 15 cm
31-016-15	Cooley Gefäß-Dilatator, Ø 1,5 mm, 15 cm	Cooley Vascular Dilator, Ø 1,5 mm, 15 cm
31-016-20	Cooley Gefäß-Dilatator, Ø 2,0 mm, 15 cm	Cooley Vascular Dilator, Ø 2,0 mm, 15 cm
31-016-25	Cooley Gefäß-Dilatator, Ø 2,5 mm, 15 cm	Cooley Vascular Dilator, Ø 2,5 mm, 15 cm
31-016-30	Cooley Gefäß-Dilatator, Ø 3,0 mm, 15 cm	Cooley Vascular Dilator, Ø 3,0 mm, 15 cm
31-016-40	Cooley Gefäß-Dilatator, Ø 4,0 mm, 15 cm	Cooley Vascular Dilator, Ø 4,0 mm, 15 cm
31-016-50	Cooley Gefäß-Dilatator, Ø 5,0 mm, 15 cm	Cooley Vascular Dilator, Ø 5,0 mm, 15 cm
31-017-05	Cooley Gefäß-Dilatator, Ø 0,5 mm, 20 cm	Cooley Vascular Dilator, Ø 0,5 mm, 20 cm
31-017-10	Cooley Gefäß-Dilatator, Ø 1,0 mm, 20 cm	Cooley Vascular Dilator, Ø 1,0 mm, 20 cm
31-017-15	Cooley Gefäß-Dilatator, Ø 1,5 mm, 20 cm	Cooley Vascular Dilator, Ø 1,5 mm, 20 cm
31-017-20	Cooley Gefäß-Dilatator, Ø 2,0 mm, 20 cm	Cooley Vascular Dilator, Ø 2,0 mm, 20 cm
31-017-25	Cooley Gefäß-Dilatator, Ø 2,5 mm, 20 cm	Cooley Vascular Dilator, Ø 2,5 mm, 20 cm
31-017-30	Cooley Gefäß-Dilatator, Ø 3,0 mm, 20 cm	Cooley Vascular Dilator, Ø 3,0 mm, 20 cm
31-017-40	Cooley Gefäß-Dilatator, Ø 4,0 mm, 20 cm	Cooley Vascular Dilator, Ø 4,0 mm, 20 cm
31-017-50	Cooley Gefäß-Dilatator, Ø 5,0 mm, 20 cm	Cooley Vascular Dilator, Ø 5,0 mm, 20 cm
31-018-05	De Bakey Gefäß-Dilatator, Ø 0,5 mm, 19cm	De Bakey Vascular Dilator,Ø0,5 mm,19cm
31-018-10	De Bakey Gefäß-Dilatator, Ø 1,0 mm, 19cm	De Bakey Vascular Dilator,Ø1,0 mm,19cm
31-018-15	De Bakey Gefäß-Dilatator, Ø 1,5 mm, 19cm	De Bakey Vascular Dilator,Ø1,5 mm,19cm
31-018-20	De Bakey Gefäß-Dilatator, Ø 2,0 mm, 19cm	De Bakey Vascular Dilator,Ø2,0 mm,19cm
31-018-25	De Bakey Gefäß-Dilatator, Ø 2,5 mm, 19cm	De Bakey Vascular Dilator,Ø2,5 mm,19cm
31-018-30	De Bakey Gefäß-Dilatator, Ø 3,0 mm, 19cm	De Bakey Vascular Dilator,Ø3,0 mm,19cm
31-018-35	De Bakey Gefäß-Dilatator, Ø 3,5 mm, 19cm	De Bakey Vascular Dilator,Ø3,5 mm,19cm
31-018-40	De Bakey Gefäß-Dilatator, Ø 4,0 mm, 19cm	De Bakey Vascular Dilator,Ø4,0 mm,19cm
31-018-45	De Bakey Gefäß-Dilatator, Ø 4,5 mm, 19cm	De Bakey Vascular Dilator,Ø4,5 mm,19cm
31-018-50	De Bakey Gefäß-Dilatator, Ø 5,0 mm, 19cm	De Bakey Vascular Dilator,Ø5,0 mm,19cm
31-018-60	De Bakey Gefäß-Dilatator, Ø 6,0 mm, 19cm	De Bakey Vascular Dilator,Ø6,0 mm,19cm

31-018-70	De Bakey Gefäß-Dilatator, Ø 7,0 mm, 19cm	De Bakey Vascular Dilator, Ø7,0 mm, 19cm
31-018-80	De Bakey Gefäß-Dilatator, Ø 8,0 mm, 19cm	De Bakey Vascular Dilator, Ø8,0 mm, 19cm
31-018-90	De Bakey Gefäß-Dilatator, Ø 9,0 mm, 19cm	De Bakey Vascular Dilator, Ø9,0 mm, 19cm
31-019-05	De Bakey Gefäß-Dilatator, Ø 0,5 mm, 35cm	De Bakey Vascular Dilator, Ø0,5 mm, 35cm
31-019-10	De Bakey Gefäß-Dilatator, Ø 1,0 mm, 35cm	De Bakey Vascular Dilator, Ø1,0 mm, 35cm
31-019-15	De Bakey Gefäß-Dilatator, Ø 1,5 mm, 35cm	De Bakey Vascular Dilator, Ø1,5 mm, 35cm
31-019-20	De Bakey Gefäß-Dilatator, Ø 2,0 mm, 35cm	De Bakey Vascular Dilator, Ø2,0 mm, 35cm
31-019-25	De Bakey Gefäß-Dilatator, Ø 2,5 mm, 35cm	De Bakey Vascular Dilator, Ø2,5 mm, 35cm
31-019-30	De Bakey Gefäß-Dilatator, Ø 3,0 mm, 35cm	De Bakey Vascular Dilator, Ø3,0 mm, 35cm
31-019-35	De Bakey Gefäß-Dilatator, Ø 3,5 mm, 35cm	De Bakey Vascular Dilator, Ø3,5 mm, 35cm
31-019-40	De Bakey Gefäß-Dilatator, Ø 4,0 mm, 35cm	De Bakey Vascular Dilator, Ø4,0 mm, 35cm
31-019-45	De Bakey Gefäß-Dilatator, Ø 4,5 mm, 35cm	De Bakey Vascular Dilator, Ø4,5 mm, 35cm
31-019-50	De Bakey Gefäß-Dilatator, Ø 5,0 mm, 35cm	De Bakey Vascular Dilator, Ø5,0 mm, 35cm
31-019-70	De Bakey Gefäß-Dilatator, Ø 7,0 mm, 35cm	De Bakey Vascular Dilator, Ø7,0 mm, 35cm
31-019-90	De Bakey Gefäß-Dilatator, Ø 9,0 mm, 35cm	De Bakey Vascular Dilator, Ø9,0 mm, 35cm
31-020-05	Garrett Gefäß-Dilatator, Ø 0,5 mm, 14 cm	Garrett Vascular Dilator, Ø 0,5 mm, 14cm
31-020-10	Garrett Gefäß-Dilatator, Ø 1,0 mm, 14 cm	Garrett Vascular Dilator, Ø 1,0 mm, 14cm
31-020-15	Garrett Gefäß-Dilatator, Ø 1,5 mm, 14 cm	Garrett Vascular Dilator, Ø 1,5 mm, 14cm
31-020-20	Garrett Gefäß-Dilatator, Ø 2,0 mm, 14 cm	Garrett Vascular Dilator, Ø 2,0 mm, 14cm
31-020-25	Garrett Gefäß-Dilatator, Ø 2,5 mm, 14 cm	Garrett Vascular Dilator, Ø 2,5 mm, 14cm
31-020-30	Garrett Gefäß-Dilatator, Ø 3,0 mm, 14 cm	Garrett Vascular Dilator, Ø 3,0 mm, 14cm
31-020-35	Garrett Gefäß-Dilatator, Ø 3,5 mm, 14 cm	Garrett Vascular Dilator, Ø 3,5 mm, 14cm
31-020-40	Garrett Gefäß-Dilatator, Ø 4,0 mm, 14 cm	Garrett Vascular Dilator, Ø 4,0 mm, 14cm
31-020-45	Garrett Gefäß-Dilatator, Ø 4,5 mm, 14 cm	Garrett Vascular Dilator, Ø 4,5 mm, 14cm
31-020-50	Garrett Gefäß-Dilatator, Ø 5,0 mm, 14 cm	Garrett Vascular Dilator, Ø 5,0 mm, 14cm
31-021-05	Garrett Gefäß-Dilatator, Ø 0,5 mm, 21 cm	Garrett Vascular Dilator, Ø 0,5 mm, 21cm
31-021-10	Garrett Gefäß-Dilatator, Ø 1,0 mm, 21 cm	Garrett Vascular Dilator, Ø 1,0 mm, 21cm
31-021-15	Garrett Gefäß-Dilatator, Ø 1,5 mm, 21 cm	Garrett Vascular Dilator, Ø 1,5 mm, 21cm
31-021-20	Garrett Gefäß-Dilatator, Ø 2,0 mm, 21 cm	Garrett Vascular Dilator, Ø 2,0 mm, 21cm
31-021-25	Garrett Gefäß-Dilatator, Ø 2,5 mm, 21 cm	Garrett Vascular Dilator, Ø 2,5 mm, 21cm
31-021-30	Garrett Gefäß-Dilatator, Ø 3,0 mm, 21 cm	Garrett Vascular Dilator, Ø 3,0 mm, 21cm
31-021-35	Garrett Gefäß-Dilatator, Ø 3,5 mm, 21 cm	Garrett Vascular Dilator, Ø 3,5 mm, 21cm
31-021-40	Garrett Gefäß-Dilatator, Ø 4,0 mm, 21 cm	Garrett Vascular Dilator, Ø 4,0 mm, 21cm
31-021-45	Garrett Gefäß-Dilatator, Ø 4,5 mm, 21 cm	Garrett Vascular Dilator, Ø 4,5 mm, 21cm
31-021-50	Garrett Gefäß-Dilatator, Ø 5,0 mm, 21 cm	Garrett Vascular Dilator, Ø 5,0 mm, 21cm
31-030-00	Tubbs Dilator, Spreizweite 8 - 42 mm	Tubbs Dilator, blade opening from 8 - 42 mm
31-032-00	Cooley Dilator, Kinder, Spreizweite 5 - 20 mm	Cooley Dilator, pediatric, blade opening from 5 - 20 mm
31-663-05	Gefäßdilator, Ø 0,5 mm, 12,5 cm	Vessel Dilator, Ø 0,5 mm, 12,5 cm
31-663-10	Gefäßdilator, Ø 1,0 mm, 12,5 cm	Vessel Dilator, Ø 1,0 mm, 12,5 cm
31-663-15	Gefäßdilator, Ø 1,5 mm, 12,5 cm	Vessel Dilator, Ø 1,5 mm, 12,5 cm
34-102-01	Bakes Dilator, biegsam, 31 cm, Ø 1 mm	Bakes Dilator, malleable, 31 cm, Ø 1 mm
34-102-02	Bakes Dilator, biegsam, 31 cm, Ø 2 mm	Bakes Dilator, malleable, 31 cm, Ø 2 mm
34-102-03	Bakes Dilator, biegsam, 31 cm, Ø 3 mm	Bakes Dilator, malleable, 31 cm, Ø 3 mm
34-102-04	Bakes Dilator, biegsam, 31 cm, Ø 4 mm	Bakes Dilator, malleable, 31 cm, Ø 4 mm
34-102-05	Bakes Dilator, biegsam, 31 cm, Ø 5 mm	Bakes Dilator, malleable, 31 cm, Ø 5 mm
34-102-06	Bakes Dilator, biegsam, 31 cm, Ø 6 mm	Bakes Dilator, malleable, 31 cm, Ø 6 mm
34-102-07	Bakes Dilator, biegsam, 31 cm, Ø 7 mm	Bakes Dilator, malleable, 31 cm, Ø 7 mm
34-102-08	Bakes Dilator, biegsam, 31 cm, Ø 8 mm	Bakes Dilator, malleable, 31 cm, Ø 8 mm
34-102-09	Bakes Dilator, biegsam, 31 cm, Ø 9 mm	Bakes Dilator, malleable, 31 cm, Ø 9 mm
34-102-10	Bakes Dilator, biegsam, 31 cm, Ø 10 mm	Bakes Dilator, malleable, 31 cm, Ø 10 mm
34-102-11	Bakes Dilator, biegsam, 31 cm, Ø 11 mm	Bakes Dilator, malleable, 31 cm, Ø 11 mm
34-102-12	Bakes Dilator, biegsam, 31 cm, Ø 12 mm	Bakes Dilator, malleable, 31 cm, Ø 12 mm
34-102-13	Bakes Dilator, biegsam, 31 cm, Ø 13 mm	Bakes Dilator, malleable, 31 cm, Ø 13 mm
35-740-09	Nabelschnur Dilator, 9,5 cm	Umbilical Cord Dilator, 9,5 cm