

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

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

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

Produktgruppe/ *Product group:* **Uterus-Dilatatoren / Dilators, Uterine**

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

Basis-UDI-DI / *Basic UDI-DI:* 4050123-35-0220-J3

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

Regel / *Rule:* 5

UMDNS: 11266 Dilator, Uterus / *Dilators, Uterine*

GMDN: 11265 Urethral dilator, reusable

EMDN: L05090201 *Gynaecological dilators*

Zweckbestimmung / *Intended use:* Schlankes, zylindrisches Instrument in verschiedenen Durchmessern zur Untersuchung des Uterus
Slim, cylindrical instrument in various diameters for the examination of the uterus

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 selbstständig durchgeführt nach Art 52, Abs. 7 und Art. 19 der Verordnung (EU) 2017/745 für Medizinprodukte der Klasse I. Wir erklären, dass wir eine Technische Dokumentation nach Anh. II und III der Verordnung (EU) 2017/745 erstellt haben und aufrechterhalten.

The Conformity Assessment Procedure has been performed self-dependent according to Art. 52, paragraph 7 and Art. 19 of the Regulation (EU) 2017/745, for class I medical devices. We confirm that we have established and maintain a technical documentation according to annex II and III of the Regulation (EU) 2017/745.

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.

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



AS Medizintechnik GmbH
 78532 Tuttlingen Sattlerstr. 15
 Tel. 07461 / 96632-6 Fax 96632-88

Tuttlingen, den 03.07.2023

Nino Schilling
 Geschäftsleitung / Managing Director

Anhang / Annex

Artikel-Nr. / Item number	Artikelbezeichnung deutsch	Articel description
35-100-01	Hegar Uterus-Dilatator Ø 1 mm, 18,5 cm	Hegar Uterine Dilator Ø 1 mm, 18,5 cm
35-100-02	Hegar Uterus-Dilatator Ø 2 mm, 18,5 cm	Hegar Uterine Dilator Ø 2 mm, 18,5 cm
35-100-03	Hegar Uterus-Dilatator Ø 3 mm, 18,5 cm	Hegar Uterine Dilator Ø 3 mm, 18,5 cm
35-100-04	Hegar Uterus-Dilatator Ø 4 mm, 18,5 cm	Hegar Uterine Dilator Ø 4 mm, 18,5 cm
35-100-05	Hegar Uterus-Dilatator Ø 5 mm, 18,5 cm	Hegar Uterine Dilator Ø 5 mm, 18,5 cm
35-100-06	Hegar Uterus-Dilatator Ø 6 mm, 18,5 cm	Hegar Uterine Dilator Ø 6 mm, 18,5 cm
35-100-07	Hegar Uterus-Dilatator Ø 7 mm, 18,5 cm	Hegar Uterine Dilator Ø 7 mm, 18,5 cm
35-100-08	Hegar Uterus-Dilatator Ø 8 mm, 18,5 cm	Hegar Uterine Dilator Ø 8 mm, 18,5 cm
35-100-09	Hegar Uterus-Dilatator Ø 9 mm, 18,5 cm	Hegar Uterine Dilator Ø 9 mm, 18,5 cm
35-100-10	Hegar Uterus-Dilatator Ø 10 mm, 18,5 cm	Hegar Uterine Dilator Ø 10 mm, 18,5 cm
35-100-11	Hegar Uterus-Dilatator Ø 11 mm, 18,5 cm	Hegar Uterine Dilator Ø 11 mm, 18,5 cm
35-100-12	Hegar Uterus-Dilatator Ø 12 mm, 18,5 cm	Hegar Uterine Dilator Ø 12 mm, 18,5 cm
35-100-13	Hegar Uterus-Dilatator Ø 13 mm, 18,5 cm	Hegar Uterine Dilator Ø 13 mm, 18,5 cm
35-100-14	Hegar Uterus-Dilatator Ø 14 mm, 18,5 cm	Hegar Uterine Dilator Ø 14 mm, 18,5 cm
35-100-15	Hegar Uterus-Dilatator Ø 15 mm, 18,5 cm	Hegar Uterine Dilator Ø 15 mm, 18,5 cm
35-100-16	Hegar Uterus-Dilatator Ø 16 mm, 18,5 cm	Hegar Uterine Dilator Ø 16 mm, 18,5 cm
35-100-17	Hegar Uterus-Dilatator Ø 17 mm, 18,5 cm	Hegar Uterine Dilator Ø 17 mm, 18,5 cm
35-100-18	Hegar Uterus-Dilatator Ø 18 mm, 18,5 cm	Hegar Uterine Dilator Ø 18 mm, 18,5 cm
35-100-19	Hegar Uterus-Dilatator Ø 19 mm, 18,5 cm	Hegar Uterine Dilator Ø 19 mm, 18,5 cm
35-100-20	Hegar Uterus-Dilatator Ø 20 mm, 18,5 cm	Hegar Uterine Dilator Ø 20 mm, 18,5 cm
35-100-21	Hegar Uterus-Dilatator Ø 21 mm, 18,5 cm	Hegar Uterine Dilator Ø 21 mm, 18,5 cm
35-100-22	Hegar Uterus-Dilatator Ø 22 mm, 18,5 cm	Hegar Uterine Dilator Ø 22 mm, 18,5 cm
35-100-23	Hegar Uterus-Dilatator Ø 23 mm, 18,5 cm	Hegar Uterine Dilator Ø 23 mm, 18,5 cm
35-100-24	Hegar Uterus-Dilatator Ø 24 mm, 18,5 cm	Hegar Uterine Dilator Ø 24 mm, 18,5 cm
35-100-25	Hegar Uterus-Dilatator Ø 25 mm, 18,5 cm	Hegar Uterine Dilator Ø 25 mm, 18,5 cm
35-100-26	Hegar Uterus-Dilatator Ø 26 mm, 18,5 cm	Hegar Uterine Dilator Ø 26 mm, 18,5 cm
35-100-27	Hegar Uterus-Dilatator Ø 27 mm, 18,5 cm	Hegar Uterine Dilator Ø 27 mm, 18,5 cm
35-100-28	Hegar Uterus-Dilatator Ø 28 mm, 18,5 cm	Hegar Uterine Dilator Ø 28 mm, 18,5 cm
35-100-29	Hegar Uterus-Dilatator Ø 29 mm, 18,5 cm	Hegar Uterine Dilator Ø 29 mm, 18,5 cm
35-100-30	Hegar Uterus-Dilatator Ø 30 mm, 18,5 cm	Hegar Uterine Dilator Ø 30 mm, 18,5 cm
35-105-01	Hegar Uterus-Dilatator Ø 1,5 mm, 18,5 cm	Hegar Uterine Dilator Ø 1,5 mm, 18,5 cm
35-105-02	Hegar Uterus-Dilatator Ø 2,5 mm, 18,5 cm	Hegar Uterine Dilator Ø 2,5 mm, 18,5 cm
35-105-03	Hegar Uterus-Dilatator Ø 3,5 mm, 18,5 cm	Hegar Uterine Dilator Ø 3,5 mm, 18,5 cm
35-105-04	Hegar Uterus-Dilatator Ø 4,5 mm, 18,5 cm	Hegar Uterine Dilator Ø 4,5 mm, 18,5 cm
35-105-05	Hegar Uterus-Dilatator Ø 5,5 mm, 18,5 cm	Hegar Uterine Dilator Ø 5,5 mm, 18,5 cm
35-105-06	Hegar Uterus-Dilatator Ø 6,5 mm, 18,5 cm	Hegar Uterine Dilator Ø 6,5 mm, 18,5 cm
35-105-07	Hegar Uterus-Dilatator Ø 7,5 mm, 18,5 cm	Hegar Uterine Dilator Ø 7,5 mm, 18,5 cm

35-105-08	Hegar Uterus-Dilatator Ø 8,5 mm, 18,5 cm	Hegar Uterine Dilator Ø 8,5 mm, 18,5 cm
35-105-09	Hegar Uterus-Dilatator Ø 9,5 mm, 18,5 cm	Hegar Uterine Dilator Ø 9,5 mm, 18,5 cm
35-105-10	Hegar Uterus-Dilatator Ø 10,5 mm, 18,5cm	Hegar Uterine Dilator Ø 10,5 mm, 18,5 cm
35-105-11	Hegar Uterus-Dilatator Ø 11,5 mm, 18,5cm	Hegar Uterine Dilator Ø 11,5 mm, 18,5 cm
35-105-12	Hegar Uterus-Dilatator Ø 12,5 mm, 18,5cm	Hegar Uterine Dilator Ø 12,5 mm, 18,5 cm
35-105-13	Hegar Uterus-Dilatator Ø 13,5 mm, 18,5cm	Hegar Uterine Dilator Ø 13,5 mm, 18,5 cm
35-105-14	Hegar Uterus-Dilatator Ø 14,5 mm, 18,5cm	Hegar Uterine Dilator Ø 14,5 mm, 18,5 cm
35-105-15	Hegar Uterus-Dilatator Ø 15,5 mm, 18,5cm	Hegar Uterine Dilator Ø 15,5 mm, 18,5 cm
35-105-16	Hegar Uterus-Dilatator Ø 16,5 mm, 18,5cm	Hegar Uterine Dilator Ø 16,5 mm, 18,5 cm
35-105-17	Hegar Uterus-Dilatator Ø 17,5 mm, 18,5cm	Hegar Uterine Dilator Ø 17,5 mm, 18,5 cm
35-105-18	Hegar Uterus-Dilatator Ø 18,5 mm, 18,5cm	Hegar Uterine Dilator Ø 18,5 mm, 18,5 cm
35-105-19	Hegar Uterus-Dilatator Ø 19,5 mm, 18,5cm	Hegar Uterine Dilator Ø 19,5 mm, 18,5 cm
35-110-02	Hegar Uterus-Dilatator, doppelseitig,Ø 1-2 mm, 20,0 cm	Hegar Uterine Dilator, double, Ø 1-2 mm,20,0 cm
35-110-04	Hegar Uterus-Dilatator, doppelseitig,Ø 3-4 mm, 20,0 cm	Hegar Uterine Dilator, double, Ø 3-4 mm,20,0 cm
35-110-06	Hegar Uterus-Dilatator, doppelseitig,Ø 5-6 mm, 20,0 cm	Hegar Uterine Dilator, double, Ø 5-6 mm,20,0 cm
35-110-08	Hegar Uterus-Dilatator, doppelseitig,Ø 7-8 mm, 20,0 cm	Hegar Uterine Dilator, double, Ø 7-8 mm,20,0 cm
35-110-10	Hegar Uterus-Dilatator, doppelseitig,Ø 9-10 mm, 20,0 cm	Hegar Uterine Dilator, double, Ø 9-10 mm20,0 cm
35-110-12	Hegar Uterus-Dilatator, doppelseitig,Ø 11-12 mm, 20,0 cm	Hegar Uterine Dilator, double, Ø 11-12mm20,0 cm
35-110-14	Hegar Uterus-Dilatator, doppelseitig,Ø 13-14 mm, 20,0 cm	Hegar Uterine Dilator, double, Ø 13-14mm20,0 cm
35-110-16	Hegar Uterus-Dilatator, doppelseitig,Ø 15-16 mm, 20,0 cm	Hegar Uterine Dilator, double, Ø 15-16mm20,0 cm
35-110-18	Hegar Uterus-Dilatator, doppelseitig,Ø 17-18 mm, 20,0 cm	Hegar Uterine Dilator, double, Ø 17-18mm20,0 cm
35-110-20	Hegar Uterus-Dilatator, doppelseitig,Ø 19-20 mm, 20,0 cm	Hegar Uterine Dilator, double, Ø 19-20mm20,0 cm
35-110-22	Hegar Uterus-Dilatator, doppelseitig,Ø 21-22 mm, 20,0 cm	Hegar Uterine Dilator, double, Ø 21-22mm20,0 cm
35-110-24	Hegar Uterus-Dilatator, doppelseitig,Ø 23-24 mm, 20,0 cm	Hegar Uterine Dilator, double, Ø 23-24mm20,0 cm
35-110-26	Hegar Uterus-Dilatator, doppelseitig,Ø 25-26 mm, 20,0 cm	Hegar Uterine Dilator, double, Ø 25-26mm20,0 cm
35-112-15	Pratt Uterus-Dilatator, doppelseitig, Fig. 13 / 15, Ø 4,5 / 5,0 mm, 28,5 cm	Pratt Uterine Dilator, double, Fig. 13 / 15, Ø 4,5 / 5,0 mm, 28,5 cm
35-112-19	Pratt Uterus-Dilatator, doppelseitig, Fig. 17 / 19, Ø 5,6 / 6,3 mm, 28,5 cm	Pratt Uterine Dilator, double, Fig. 17 / 19, Ø 5,6 / 6,3 mm, 28,5 cm
35-112-23	Pratt Uterus-Dilatator, doppelseitig, Fig. 21 / 23, Ø 7,0 / 7,6 mm, 28,5 cm	Pratt Uterine Dilator, double, Fig. 21 / 23, Ø 7,0 / 7,6 mm, 28,5 cm
35-112-27	Pratt Uterus-Dilatator, doppelseitig, Fig. 25 / 27, Ø 8,3 / 9,0 mm, 28,5 cm	Pratt Uterine Dilator, double, Fig. 25 / 27, Ø 8,3 / 9,0 mm, 28,5 cm
35-112-31	Pratt Uterus-Dilatator, doppelseitig, Fig. 29 / 31, Ø 9,6 / 10,3 mm, 28,5 cm	Pratt Uterine Dilator, double, Fig. 29 / 31, Ø 9,6 / 10,3 mm, 28,5 cm
35-112-35	Pratt Uterus-Dilatator, doppelseitig, Fig. 33 / 35, Ø 11,0 / 11,6 mm, 28,5 cm	Pratt Uterine Dilator, double, Fig. 33 / 35, Ø 11,0 / 11,6 mm, 28,5 cm
35-112-39	Pratt Uterus-Dilatator, doppelseitig, Fig. 37 / 39, Ø 12,3 / 13,0 mm, 28,5 cm	Pratt Uterine Dilator, double, Fig. 37 / 39, Ø 12,3 / 13,0 mm, 28,5 cm
35-112-43	Pratt Uterus-Dilatator, doppelseitig, Fig. 41 / 43, Ø 13,6 / 14,3 mm, 28,5 cm	Pratt Uterine Dilator, double, Fig. 41 / 43, Ø 13,6 / 14,3 mm, 28,5 cm
35-115-10	Hank Uterus-Dilatator, doppelseitig, Fig. 9 / 10, Ø 4,5 / 5,0 mm, 27,5 cm	Hank Uterine Dilator, double, Fig. 9 / 10, Ø 4,5 / 5,0 mm, 27,5 cm
35-115-12	Hank Uterus-Dilatator, doppelseitig, Fig. 11 / 12, Ø 5,5 / 6,0 mm, 27,5 cm	Hank Uterine Dilator, double, Fig. 11 / 12, Ø 5,5 / 6,0 mm, 27,5 cm
35-115-14	Hank Uterus-Dilatator, doppelseitig, Fig. 13 / 14, Ø 6,5 / 7,0 mm, 27,5 cm	Hank Uterine Dilator, double, Fig. 13 / 14, Ø 6,5 / 7,0 mm, 27,5 cm
35-115-16	Hank Uterus-Dilatator, doppelseitig, Fig. 15 / 16, Ø 7,5 / 8,0 mm, 27,5 cm	Hank Uterine Dilator, double, Fig. 15 / 16, Ø 7,5 / 8,0 mm, 27,5 cm
35-115-18	Hank Uterus-Dilatator, doppelseitig, Fig. 17 / 18, Ø 8,5 / 9,0 mm, 27,5 cm	Hank Uterine Dilator, double, Fig. 17 / 18, Ø 8,5 / 9,0 mm, 27,5 cm
35-115-20	Hank Uterus-Dilatator, doppelseitig, Fig. 19 / 20, Ø 9,5 / 10,0 mm, 27,5 cm	Hank Uterine Dilator, double, Fig. 19 / 20, Ø 9,5 / 10,0 mm, 27,5 cm
35-150-34	Goodell Uterusdilator, 34 cm	Goodell Uterine Dilator, 34 cm