

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

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

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

Produktgruppe/ *Product group:* **Chirurgische Nadeln / Surgical needles**

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

Basis-UDI-DI / *Basic UDI-DI:* 4050123-17-0160-JC

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

Regel / *Rule:* 6

UMDNS: 12754 Nadel, Wundnaht / *Needles, Suture*

GMDN: 32357 *Suturing needle, reusable*

EMDN: L0202 *Suture needles, reusable*

Zweckbestimmung / *Intended use:* Chirurgische Nadeln für die Verwendung bei der Wundnaht.
Surgical needles for use in wound suturing.

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
17-803-01	Chir. Nadel, "B", dreikant, gebogen, Fig. 1, 3/8 Kreis, VE = 12 Stück	Surgical needle, "B", triangular, curved Fig. 1, 3/8 circle, Unit = 12 pcs.
17-803-02	Chir. Nadel, "B", dreikant, gebogen, Fig. 2, 3/8 Kreis, VE = 12 Stück	Surgical needle, "B", triangular, curved Fig. 2, 3/8 circle, Unit = 12 pcs.
17-803-03	Chir. Nadel, "B", dreikant, gebogen, Fig. 3, 3/8 Kreis, VE = 12 Stück	Surgical needle, "B", triangular, curved Fig. 3, 3/8 circle, Unit = 12 pcs.
17-803-04	Chir. Nadel, "B", dreikant, gebogen, Fig. 4, 3/8 Kreis, VE = 12 Stück	Surgical needle, "B", triangular, curved Fig. 4, 3/8 circle, Unit = 12 pcs.
17-803-05	Chir. Nadel, "B", dreikant, gebogen, Fig. 5, 3/8 Kreis, VE = 12 Stück	Surgical needle, "B", triangular, curved Fig. 5, 3/8 circle, Unit = 12 pcs.
17-803-06	Chir. Nadel, "B", dreikant, gebogen, Fig. 6, 3/8 Kreis, VE = 12 Stück	Surgical needle, "B", triangular, curved Fig. 6, 3/8 circle, Unit = 12 pcs.
17-803-07	Chir. Nadel, "B", dreikant, gebogen, Fig. 7, 3/8 Kreis, VE = 12 Stück	Surgical needle, "B", triangular, curved Fig. 7, 3/8 circle, Unit = 12 pcs.
17-803-08	Chir. Nadel, "B", dreikant, gebogen, Fig. 8, 3/8 Kreis, VE = 12 Stück	Surgical needle, "B", triangular, curved Fig. 8, 3/8 circle, Unit = 12 pcs.
17-803-09	Chir. Nadel, "B", dreikant, gebogen, Fig. 9, 3/8 Kreis, VE = 12 Stück	Surgical needle, "B", triangular, curved Fig. 9, 3/8 circle, Unit = 12 pcs.
17-803-10	Chir. Nadel, "B", dreikant, gebogen, Fig. 10, 3/8 Kreis, VE = 12 Stück	Surgical needle, "B", triangular, curved Fig. 10, 3/8 circle, Unit = 12 pcs.
17-803-11	Chir. Nadel, "B", dreikant, gebogen, Fig. 11, 3/8 Kreis, VE = 12 Stück	Surgical needle, "B", triangular, curved Fig. 11, 3/8 circle, Unit = 12 pcs.
17-803-12	Chir. Nadel, "B", dreikant, gebogen, Fig. 12, 3/8 Kreis, VE = 12 Stück	Surgical needle, "B", triangular, curved Fig. 12, 3/8 circle, Unit = 12 pcs.
17-803-13	Chir. Nadel, "B", dreikant, gebogen, Fig. 13, 3/8 Kreis, VE = 12 Stück	Surgical needle, "B", triangular, curved Fig. 13, 3/8 circle, Unit = 12 pcs.
17-803-14	Chir. Nadel, "B", dreikant, gebogen, Fig. 14, 3/8 Kreis, VE = 12 Stück	Surgical needle, "B", triangular, curved Fig. 14, 3/8 circle, Unit = 12 pcs.
17-803-15	Chir. Nadel, "B", dreikant, gebogen, Fig. 15, 3/8 Kreis, VE = 12 Stück	Surgical needle, "B", triangular, curved Fig. 15, 3/8 circle, Unit = 12 pcs.
17-803-16	Chir. Nadel, "B", dreikant, gebogen, Fig. 16, 3/8 Kreis, VE = 12 Stück	Surgical needle, "B", triangular, curved Fig. 16, 3/8 circle, Unit = 12 pcs.
17-817-01	Chir. Nadel, "G", dreikant, gebogen, Fig. 1, 1/2 Kreis, VE = 12 Stück	Surgical needle, "G", triangular, curved Fig. 1, 1/2 circle, Unit = 12 pcs.
17-817-02	Chir. Nadel, "G", dreikant, gebogen, Fig. 2, 1/2 Kreis, VE = 12 Stück	Surgical needle, "G", triangular, curved Fig. 2, 1/2 circle, Unit = 12 pcs.
17-817-03	Chir. Nadel, "G", dreikant, gebogen, Fig. 3, 1/2 Kreis, VE = 12 Stück	Surgical needle, "G", triangular, curved Fig. 3, 1/2 circle, Unit = 12 pcs.
17-817-04	Chir. Nadel, "G", dreikant, gebogen, Fig. 4, 1/2 Kreis, VE = 12 Stück	Surgical needle, "G", triangular, curved Fig. 4, 1/2 circle, Unit = 12 pcs.
17-817-05	Chir. Nadel, "G", dreikant, gebogen, Fig. 5, 1/2 Kreis, VE = 12 Stück	Surgical needle, "G", triangular, curved Fig. 5, 1/2 circle, Unit = 12 pcs.
17-817-06	Chir. Nadel, "G", dreikant, gebogen, Fig. 6, 1/2 Kreis, VE = 12 Stück	Surgical needle, "G", triangular, curved Fig. 6, 1/2 circle, Unit = 12 pcs.
17-817-07	Chir. Nadel, "G", dreikant, gebogen, Fig. 7, 1/2 Kreis, VE = 12 Stück	Surgical needle, "G", triangular, curved Fig. 7, 1/2 circle, Unit = 12 pcs.
17-817-08	Chir. Nadel, "G", dreikant, gebogen, Fig. 8, 1/2 Kreis, VE = 12 Stück	Surgical needle, "G", triangular, curved Fig. 8, 1/2 circle, Unit = 12 pcs.

17-817-09	Chir. Nadel, "G", dreikant, gebogen, Fig. 9, 1/2 Kreis, VE = 12 Stück	Surgical needle, "G", triangular, curved Fig. 9, 1/2 circle, Unit = 12 pcs.
17-817-10	Chir. Nadel, "G", dreikant, gebogen, Fig. 10, 1/2 Kreis, VE = 12 Stück	Surgical needle, "G", triangular, curved Fig. 10, 1/2 circle, Unit = 12 pcs.
17-817-11	Chir. Nadel, "G", dreikant, gebogen, Fig. 11, 1/2 Kreis, VE = 12 Stück	Surgical needle, "G", triangular, curved Fig. 11, 1/2 circle, Unit = 12 pcs.
17-817-12	Chir. Nadel, "G", dreikant, gebogen, Fig. 12, 1/2 Kreis, VE = 12 Stück	Surgical needle, "G", triangular, curved Fig. 12, 1/2 circle, Unit = 12 pcs.
17-817-13	Chir. Nadel, "G", dreikant, gebogen, Fig. 13, 1/2 Kreis, VE = 12 Stück	Surgical needle, "G", triangular, curved Fig. 13, 1/2 circle, Unit = 12 pcs.
17-817-14	Chir. Nadel, "G", dreikant, gebogen, Fig. 14, 1/2 Kreis, VE = 12 Stück	Surgical needle, "G", triangular, curved Fig. 14, 1/2 circle, Unit = 12 pcs.
17-817-15	Chir. Nadel, "G", dreikant, gebogen, Fig. 15, 1/2 Kreis, VE = 12 Stück	Surgical needle, "G", triangular, curved Fig. 15, 1/2 circle, Unit = 12 pcs.
17-817-16	Chir. Nadel, "G", dreikant, gebogen, Fig. 16, 1/2 Kreis, VE = 12 Stück	Surgical needle, "G", triangular, curved Fig. 16, 1/2 circle, Unit = 12 pcs.
17-818-01	Chir. Nadel, "Gr", rund, gebogen, Fig. 1, 1/2 Kreis, VE = 12 Stück	Surgical needle, "Gr", round, curved, Fig. 1, 1/2 circle, Unit = 12 pcs.
17-818-02	Chir. Nadel, "Gr", rund, gebogen, Fig. 2, 1/2 Kreis, VE = 12 Stück	Surgical needle, "Gr", round, curved, Fig. 2, 1/2 circle, Unit = 12 pcs.
17-818-03	Chir. Nadel, "Gr", rund, gebogen, Fig. 3, 1/2 Kreis, VE = 12 Stück	Surgical needle, "Gr", round, curved, Fig. 3, 1/2 circle, Unit = 12 pcs.
17-818-04	Chir. Nadel, "Gr", rund, gebogen, Fig. 4, 1/2 Kreis, VE = 12 Stück	Surgical needle, "Gr", round, curved, Fig. 4, 1/2 circle, Unit = 12 pcs.
17-818-05	Chir. Nadel, "Gr", rund, gebogen, Fig. 5, 1/2 Kreis, VE = 12 Stück	Surgical needle, "Gr", round, curved, Fig. 5, 1/2 circle, Unit = 12 pcs.
17-818-06	Chir. Nadel, "Gr", rund, gebogen, Fig. 6, 1/2 Kreis, VE = 12 Stück	Surgical needle, "Gr", round, curved, Fig. 6, 1/2 circle, Unit = 12 pcs.
17-818-07	Chir. Nadel, "Gr", rund, gebogen, Fig. 7, 1/2 Kreis, VE = 12 Stück	Surgical needle, "Gr", round, curved, Fig. 7, 1/2 circle, Unit = 12 pcs.
17-818-08	Chir. Nadel, "Gr", rund, gebogen, Fig. 8, 1/2 Kreis, VE = 12 Stück	Surgical needle, "Gr", round, curved, Fig. 8, 1/2 circle, Unit = 12 pcs.
17-818-09	Chir. Nadel, "Gr", rund, gebogen, Fig. 9, 1/2 Kreis, VE = 12 Stück	Surgical needle, "Gr", round, curved, Fig. 9, 1/2 circle, Unit = 12 pcs.
17-818-10	Chir. Nadel, "Gr", rund, gebogen, Fig. 10, 1/2 Kreis, VE = 12 Stück	Surgical needle, "Gr", round, curved, Fig. 10, 1/2 circle, Unit = 12 pcs.
17-818-11	Chir. Nadel, "Gr", rund, gebogen, Fig. 11, 1/2 Kreis, VE = 12 Stück	Surgical needle, "Gr", round, curved, Fig. 11, 1/2 circle, Unit = 12 pcs.
17-818-12	Chir. Nadel, "Gr", rund, gebogen, Fig. 12, 1/2 Kreis, VE = 12 Stück	Surgical needle, "Gr", round, curved, Fig. 12, 1/2 circle, Unit = 12 pcs.
17-818-13	Chir. Nadel, "Gr", rund, gebogen, Fig. 13, 1/2 Kreis, VE = 12 Stück	Surgical needle, "Gr", round, curved, Fig. 13, 1/2 circle, Unit = 12 pcs.
17-818-14	Chir. Nadel, "Gr", rund, gebogen, Fig. 14, 1/2 Kreis, VE = 12 Stück	Surgical needle, "Gr", round, curved, Fig. 14, 1/2 circle, Unit = 12 pcs.
17-818-15	Chir. Nadel, "Gr", rund, gebogen, Fig. 15, 1/2 Kreis, VE = 12 Stück	Surgical needle, "Gr", round, curved, Fig. 15, 1/2 circle, Unit = 12 pcs.
17-818-16	Chir. Nadel, "Gr", rund, gebogen, Fig. 16, 1/2 Kreis, VE = 12 Stück	Surgical needle, "Gr", round, curved, Fig. 16, 1/2 circle, Unit = 12 pcs.
17-819-01	Chir. Nadel, "Ga", dreikant, gebogen, Fig. 1, 1/2 Kreis, VE = 12 Stück	Surgical needle, "Ga", triangular, cvd., Fig. 1, 1/2 circle, Unit = 12 pcs.
17-819-02	Chir. Nadel, "Ga", dreikant, gebogen, Fig. 2, 1/2 Kreis, VE = 12 Stück	Surgical needle, "Ga", triangular, cvd., Fig. 2, 1/2 circle, Unit = 12 pcs.
17-819-03	Chir. Nadel, "Ga", dreikant, gebogen, Fig. 3, 1/2 Kreis, VE = 12 Stück	Surgical needle, "Ga", triangular, cvd., Fig. 3, 1/2 circle, Unit = 12 pcs.
17-819-04	Chir. Nadel, "Ga", dreikant, gebogen, Fig. 4, 1/2 Kreis, VE = 12 Stück	Surgical needle, "Ga", triangular, cvd., Fig. 4, 1/2 circle, Unit = 12 pcs.
17-819-05	Chir. Nadel, "Ga", dreikant, gebogen, Fig. 5, 1/2 Kreis, VE = 12 Stück	Surgical needle, "Ga", triangular, cvd., Fig. 5, 1/2 circle, Unit = 12 pcs.
17-819-06	Chir. Nadel, "Ga", dreikant, gebogen, Fig. 6, 1/2 Kreis, VE = 12 Stück	Surgical needle, "Ga", triangular, cvd., Fig. 6, 1/2 circle, Unit = 12 pcs.
17-819-07	Chir. Nadel, "Ga", dreikant, gebogen, Fig. 7, 1/2 Kreis, VE = 12 Stück	Surgical needle, "Ga", triangular, cvd., Fig. 7, 1/2 circle, Unit = 12 pcs.
17-819-08	Chir. Nadel, "Ga", dreikant, gebogen, Fig. 8, 1/2 Kreis, VE = 12 Stück	Surgical needle, "Ga", triangular, cvd., Fig. 8, 1/2 circle, Unit = 12 pcs.
17-819-09	Chir. Nadel, "Ga", dreikant, gebogen, Fig. 9, 1/2 Kreis, VE = 12 Stück	Surgical needle, "Ga", triangular, cvd., Fig. 9, 1/2 circle, Unit = 12 pcs.
17-825-01	Chir. Nadel, "Keith", dreikant, gerade, Fig. 1, VE = 12 Stück	Surgical needle, "Keith", triangular, straight, Fig. 1, Unit = 12 pcs.
17-825-02	Chir. Nadel, "Keith", dreikant, gerade, Fig. 2, VE = 12 Stück	Surgical needle, "Keith", triangular, straight, Fig. 2, Unit = 12 pcs.

17-825-03	Chir. Nadel, "Keith", dreikant, gerade, Fig. 3, VE = 12 Stück	Surgical needle, "Keith", triangular, straight, Fig. 3, Unit = 12 pcs.
17-825-04	Chir. Nadel, "Keith", dreikant, gerade, Fig. 4, VE = 12 Stück	Surgical needle, "Keith", triangular, straight, Fig. 4, Unit = 12 pcs.
17-825-05	Chir. Nadel, "Keith", dreikant, gerade, Fig. 5, VE = 12 Stück	Surgical needle, "Keith", triangular, straight, Fig. 5, Unit = 12 pcs.
17-825-06	Chir. Nadel, "Keith", dreikant, gerade, Fig. 6, VE = 12 Stück	Surgical needle, "Keith", triangular, straight, Fig. 6, Unit = 12 pcs.
17-826-01	Chir. Nadel, "Keith", rund, gerade, Fig. 1, VE = 12 Stück	Surgical needle, "Keith", round, straight, Fig. 1, Unit = 12 pcs.
17-826-02	Chir. Nadel, "Keith", rund, gerade, Fig. 2, VE = 12 Stück	Surgical needle, "Keith", round, straight, Fig. 2, Unit = 12 pcs.
17-826-03	Chir. Nadel, "Keith", rund, gerade, Fig. 3, VE = 12 Stück	Surgical needle, "Keith", round, straight, Fig. 3, Unit = 12 pcs.
17-826-04	Chir. Nadel, "Keith", rund, gerade, Fig. 4, VE = 12 Stück	Surgical needle, "Keith", round, straight, Fig. 4, Unit = 12 pcs.
17-826-05	Chir. Nadel, "Keith", rund, gerade, Fig. 5, VE = 12 Stück	Surgical needle, "Keith", round, straight, Fig. 5, Unit = 12 pcs.
17-826-06	Chir. Nadel, "Keith", rund, gerade, Fig. 6, VE = 12 Stück	Surgical needle, "Keith", round, straight, Fig. 6, Unit = 12 pcs.
17-851-02	Chir. Nadel, "Pb", rund, gebogen, Fig. 00, 1/2 Kreis, VE = 12 Stück	Surgical needle, "Pb", round, curved, Fig. 00, 1/2 circle, Unit = 12 pcs.
17-851-03	Chir. Nadel, "Pb", rund, gebogen, Fig. 0, 1/2 Kreis, VE = 12 Stück	Surgical needle, "Pb", round, curved, Fig. 0, 1/2 circle, Unit = 12 pcs.
17-853-01	Chir. Nadel, "Pb", rund, gebogen, Fig. 1, 1/2 Kreis, VE = 12 Stück	Surgical needle, "Pb", round, curved, Fig. 1, 1/2 circle, Unit = 12 pcs.
17-853-02	Chir. Nadel, "Pb", rund, gebogen, Fig. 2, 1/2 Kreis, VE = 12 Stück	Surgical needle, "Pb", round, curved, Fig. 2, 1/2 circle, Unit = 12 pcs.
17-853-03	Chir. Nadel, "Pb", rund, gebogen, Fig. 3, 1/2 Kreis, VE = 12 Stück	Surgical needle, "Pb", round, curved, Fig. 3, 1/2 circle, Unit = 12 pcs.
17-853-04	Chir. Nadel, "Pb", rund, gebogen, Fig. 4, 1/2 Kreis, VE = 12 Stück	Surgical needle, "Pb", round, curved, Fig. 4, 1/2 circle, Unit = 12 pcs.
17-853-05	Chir. Nadel, "Pb", rund, gebogen, Fig. 5, 1/2 Kreis, VE = 12 Stück	Surgical needle, "Pb", round, curved, Fig. 5, 1/2 circle, Unit = 12 pcs.
17-853-06	Chir. Nadel, "Pb", rund, gebogen, Fig. 6, 1/2 Kreis, VE = 12 Stück	Surgical needle, "Pb", round, curved, Fig. 6, 1/2 circle, Unit = 12 pcs.
17-853-07	Chir. Nadel, "Pb", rund, gebogen, Fig. 7, 1/2 Kreis, VE = 12 Stück	Surgical needle, "Pb", round, curved, Fig. 7, 1/2 circle, Unit = 12 pcs.
17-853-08	Chir. Nadel, "Pb", rund, gebogen, Fig. 8, 1/2 Kreis, VE = 12 Stück	Surgical needle, "Pb", round, curved, Fig. 8, 1/2 circle, Unit = 12 pcs.
17-855-02	Darmnadel "Pd", rund, gebogen, Fig. 00, 3/8 Kreis, VE = 12 Stück	Intestinal needle, "Pd", round, curved, Fig. 00, 3/8 circle, Unit = 12 pcs.
17-855-03	Darmnadel "Pd", rund, gebogen, Fig. 0, 3/8 Kreis, VE = 12 Stück	Intestinal needle, "Pd", round, curved, Fig. 0, 3/8 circle, Unit = 12 pcs.
17-857-01	Darmnadel "Pd", rund, gebogen, Fig. 1, 3/8 Kreis, VE = 12 Stück	Intestinal needle, "Pd", round, curved, Fig. 1, 3/8 circle, Unit = 12 pcs.
17-857-02	Darmnadel "Pd", rund, gebogen, Fig. 2, 3/8 Kreis, VE = 12 Stück	Intestinal needle, "Pd", round, curved, Fig. 2, 3/8 circle, Unit = 12 pcs.
17-857-03	Darmnadel "Pd", rund, gebogen, Fig. 3, 3/8 Kreis, VE = 12 Stück	Intestinal needle, "Pd", round, curved, Fig. 3, 3/8 circle, Unit = 12 pcs.
17-857-04	Darmnadel "Pd", rund, gebogen, Fig. 4, 3/8 Kreis, VE = 12 Stück	Intestinal needle, "Pd", round, curved, Fig. 4, 3/8 circle, Unit = 12 pcs.
17-857-05	Darmnadel "Pd", rund, gebogen, Fig. 5, 3/8 Kreis, VE = 12 Stück	Intestinal needle, "Pd", round, curved, Fig. 5, 3/8 circle, Unit = 12 pcs.