

Konformitätserklärung

Declaration of Conformity

Wir / We Fuhrmann GmbH
 Bövingen 139
 D-53804 Much

SRN: DE-MF-000006652

erklären in alleiniger Verantwortung, dass das Produkt (die Produktgruppe)
hereby declare under our sole responsibility, that the device (group of devices)

Mullkompressen ohne Röntgenkontrast, unsteril ***Gauze swabs without x-ray thread, non-sterile***

die Grundlegenden Sicherheits- und Leistungsanforderungen gemäß Anhang I der Verordnung (EU) 2017/745 erfüllt.

meets the general safety and performance requirements defined in annex I of the Regulation (EU) 2017/745.

Das Konformitätsbewertungsverfahren wurde nach den Artikeln 52(7) und 19 der Verordnung (EU) 2017/745 durchgeführt. Eine Technische Dokumentation wurde erstellt und wird aufrechterhalten.

The conformity assessment procedure has been performed according to Articles 52(7) and 19 of the Regulation (EU) 2017/745. A technical documentation has been prepared and is maintained.

Klassifizierung, Regel
Classification, Rule

Klasse I, Regel 4, per Anhang VIII der Verordnung (EU) 2017/745
Class I, Rule 4, per annex VIII of Regulation (EU) 2017/745

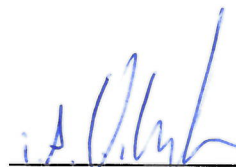
Basis-UDI-DI
Basic-UDI-DI

40548580111V0401L5

Artikelnummern
Reference Numbers

Siehe Anlage I
See Annex I

Much, 24.06.2021
Ort, Datum
Place, Date



i.A. Kristina Wrede
Qualitätsmanagement / Regulatory Affairs
Quality Management / Regulatory Affairs

Konformitätserklärung

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Anlage I

Annex I

REF	Produktbezeichnung <i>Device description</i>
10001	Mullkompressen, 5 x 5 cm, 8-fach, VM 17, unsteril <i>Gauze swab, 5 x 5 cm, 8-ply, 17 threads, non-sterile</i>
10002	Mullkompressen, 5 x 5 cm, 12-fach, VM 17, unsteril <i>Gauze swab, 5 x 5 cm, 12-ply, 17 threads, non-sterile</i>
10003	Mullkompressen, 5 x 5 cm, 16-fach, VM 17, unsteril <i>Gauze swab, 5 x 5 cm, 16-ply, 17 threads, non-sterile</i>
10011	Mullkompressen, 7,5 x 7,5 cm, 8-fach, VM 17, unsteril <i>Gauze swab, 7,5 x 7,5 cm, 8-ply, 17 threads, non-sterile</i>
10012	Mullkompressen, 7,5 x 7,5 cm, 12-fach, VM 17, unsteril <i>Gauze swab, 7,5 x 7,5 cm, 12-ply, 17 threads, non-sterile</i>
10013	Mullkompressen, 7,5 x 7,5 cm, 16-fach, VM 17, unsteril <i>Gauze swab, 7,5 x 7,5 cm, 16-ply, 17 threads, non-sterile</i>
10021	Mullkompressen, 10 x 10 cm, 8-fach, VM 17, unsteril <i>Gauze swab, 10 x 10 cm, 8-ply, 17 threads, non-sterile</i>
10022	Mullkompressen, 10 x 10 cm, 12-fach, VM 17, unsteril <i>Gauze swab, 10 x 10 cm, 12-ply, 17 threads, non-sterile</i>
10023	Mullkompressen, 10 x 10 cm, 16-fach, VM 17, unsteril <i>Gauze swab, 10 x 10 cm, 16-ply, 17 threads, non-sterile</i>
10024	Mullkompressen, 10 x 10 cm, 32-fach, VM 17, unsteril <i>Gauze swab, 10 x 10 cm, 32-ply, 17 threads, non-sterile</i>
10032	Mullkompressen, 10 x 13 cm, 12-fach, VM 17, unsteril <i>Gauze swab, 10 x 13 cm, 12-ply, 17 threads, non-sterile</i>
10041	Mullkompressen, 10 x 20 cm, 8-fach, VM 17, unsteril <i>Gauze swab, 10 x 20 cm, 8-ply, 17 threads, non-sterile</i>
10042	Mullkompressen, 10 x 20 cm, 12-fach, VM 17, unsteril <i>Gauze swab, 10 x 20 cm, 12-ply, 17 threads, non-sterile</i>
10043	Mullkompressen, 10 x 20 cm, 16-fach, VM 17, unsteril <i>Gauze swab, 10 x 20 cm, 16-ply, 17 threads, non-sterile</i>
10044	Mullkompressen, 12,5 x 20 cm, 32-fach, VM 17, unsteril <i>Gauze swab, 12,5 x 20 cm, 32-ply, 17 threads, non-sterile</i>
10045	Mullkompressen, 20 x 25 cm, 16-fach, VM 17, unsteril <i>Gauze swab, 20 x 25 cm, 16-ply, 17 threads, non-sterile</i>
10052	Mullkompressen, 25 x 25cm, 16-fach, VM 17, unsteril <i>Gauze swab, 25 x 25 cm, 16-ply, 17 threads, non-sterile</i>
19001	Mullkompressen, 5 x 5 cm, 8-fach, VM 17, unsteril <i>Gauze swab, 5 x 5 cm, 8-ply, 17 threads, non-sterile</i>
19002	Mullkompressen, 5 x 5 cm, 12-fach, VM 17, unsteril <i>Gauze swab, 5 x 5 cm, 12-ply, 17 threads, non-sterile</i>

REF	Produktbezeichnung <i>Device description</i>
19003	Mullkompressen, 5 x 5 cm, 16-fach, VM 17, unsteril <i>Gauze swab, 5 x 5 cm, 16-ply, 17 threads, non-sterile</i>
19011	Mullkompressen, 7,5 x 7,5 cm, 8-fach, VM 17, unsteril <i>Gauze swab, 7,5 x 7,5 cm, 8-ply, 17 threads, non-sterile</i>
19012	Mullkompressen, 7,5 x 7,5 cm, 12-fach, VM 17, unsteril <i>Gauze swab, 7,5 x 7,5 cm, 12-ply, 17 threads, non-sterile</i>
19013	Mullkompressen, 7,5 x 7,5 cm, 16-fach, VM 17, unsteril <i>Gauze swab, 7,5 x 7,5 cm, 16-ply, 17 threads, non-sterile</i>
19021	Mullkompressen, 10 x 10 cm, 8-fach, VM 17, unsteril <i>Gauze swab, 10 x 10 cm, 8-ply, 17 threads, non-sterile</i>
19022	Mullkompressen, 10 x 10 cm, 12-fach, VM 17, unsteril <i>Gauze swab, 10 x 10 cm, 12-ply, 17 threads, non-sterile</i>
19023	Mullkompressen, 10 x 10 cm, 16-fach, VM 17, unsteril <i>Gauze swab, 10 x 10 cm, 16-ply, 17 threads, non-sterile</i>
19024	Mullkompressen, 10 x 10 cm, 32-fach, VM 17, unsteril <i>Gauze swab, 10 x 10 cm, 32-ply, 17 threads, non-sterile</i>
19032	Mullkompressen, 10 x 13 cm, 12-fach, VM 17, unsteril <i>Gauze swab, 10 x 13 cm, 12-ply, 17 threads, non-sterile</i>
19041	Mullkompressen, 10 x 20 cm, 8-fach, VM 17, unsteril <i>Gauze swab, 10 x 20 cm, 8-ply, 17 threads, non-sterile</i>
19042	Mullkompressen, 10 x 20 cm, 12-fach, VM 17, unsteril <i>Gauze swab, 10 x 20 cm, 12-ply, 17 threads, non-sterile</i>