

Konformitätserklärung

Declaration of Conformity

Wir / we Fuhrmann GmbH
 Bövingen 139
 D-53804 Much

SRN: noch nicht verfügbar
 not yet available

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, 26.05.2021
Ort, Datum
Place, Date



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

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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> |