

Title: J 5.4 Declaration of conformity

EU-Konformitätserklärung EU Declaration of Conformity

Der Unterzeichner, der den nachstehenden Hersteller vertritt,
The signatory, who represents the below-mentioned manufacturer,

Hersteller / *Manufacturer*

Ottobock SE & Co. KGaA
Max-Näder-Str. 15
37115 Duderstadt
Germany

SRN: N/A

erklärt hiermit in alleiniger Verantwortung, dass das Produkt
herewith declares under his sole responsibility that the product

Produkt / *Product*

8S711=*

bebionic Silicone Glove
Risikoklasse I
gemäß Verordnung (EU) 2017/745
Basis-UDI-DI (GMN):
40644110000000008S711PG

bebionic Silicone Glove
Risk class I
according to Regulation (EU) 2017/745
Basic UDI-DI (GMN):
40644110000000008S711PG

in folgenden Varianten
in the following variants

Varianten / *Variants*

8S711=L-L02	8S711=L-M09	8S711=R-L02	8S711=R-M09
8S711=L-L03	8S711=L-M11	8S711=R-L03	8S711=R-M11
8S711=L-L04	8S711=L-M14	8S711=R-L04	8S711=R-M14
8S711=L-L06	8S711=L-M16	8S711=R-L06	8S711=R-M16
8S711=L-L09	8S711=L-S02	8S711=R-L09	8S711=R-S02
8S711=L-L11	8S711=L-S03	8S711=R-L11	8S711=R-S03
8S711=L-L14	8S711=L-S04	8S711=R-L14	8S711=R-S04
8S711=L-L16	8S711=L-S06	8S711=R-L16	8S711=R-S06
8S711=L-M02	8S711=L-S09	8S711=R-M02	8S711=R-S09
8S711=L-M03	8S711=L-S11	8S711=R-M03	8S711=R-S11
8S711=L-M04	8S711=L-S14	8S711=R-M04	8S711=R-S14
8S711=L-M06	8S711=L-S16	8S711=R-M06	8S711=R-S16
8S711=L-L02-N	8S711=L-M09-N	8S711=R-L02-N	8S711=R-M09-N
8S711=L-L03-N	8S711=L-M11-N	8S711=R-L03-N	8S711=R-M11-N
8S711=L-L04-N	8S711=L-M14-N	8S711=R-L04-N	8S711=R-M14-N
8S711=L-L06-N	8S711=L-M16-N	8S711=R-L06-N	8S711=R-M16-N
8S711=L-L09-N	8S711=L-S02-N	8S711=R-L09-N	8S711=R-S02-N
8S711=L-L11-N	8S711=L-S03-N	8S711=R-L11-N	8S711=R-S03-N
8S711=L-L14-N	8S711=L-S04-N	8S711=R-L14-N	8S711=R-S04-N
8S711=L-L16-N	8S711=L-S06-N	8S711=R-L16-N	8S711=R-S06-N
8S711=L-M02-N	8S711=L-S09-N	8S711=R-M02-N	8S711=R-S09-N
8S711=L-M03-N	8S711=L-S11-N	8S711=R-M03-N	8S711=R-S11-N
8S711=L-M04-N	8S711=L-S14-N	8S711=R-M04-N	8S711=R-S14-N
8S711=L-M06-N	8S711=L-S16-N	8S711=R-M06-N	8S711=R-S16-N

mit den Bestimmungen der nachstehenden EU-Verordnung(en), EU-Richtlinie(n) und Gemeinsame Spezifikation(en) übereinstimmt.
is in conformity with the relevant provisions of below-mentioned EC Regulation(s), EC Directive(s) and Common Specification(s).

2017/745 EU Verordnung des Europäischen Parlaments und des Rates über Medizinprodukte
Regulation of the European Parliament and of the Council on medical devices

Gemeinsame Spezifikation(en) / Common specification(s): N/A

Die Konformität wird erklärt nach Artikel 52(7), Anhang II und III der Verordnung (EU) 2017/745.
The conformity is declared based on Article 52(7), Annex II and III of the Regulation (EU) 2017/745.

Duderstadt, 2021-06-18

Ort, Datum / *Place, Date*

Andreas Goppelt
Geschäftsführer
Managing Director

Dominik Schmidt
Für die Einhaltung der Regulierungsvorschriften
verantwortliche Person
Person Responsible for Regulatory Compliance

Aufzeichnungshistorie/ *Document history*

Effective date	Reason for change	Comments
2021-06-18	New variants included (*N)	V2
2021-04-09	Initial version	V1