

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, D-37115 Duderstadt

SRN: N/A

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

Produkt / *Product:*

1C11*

Terion K2 / Terion K2

Klasse / Class I according to 2017/745 EU, Annex VIII

GMDN: 41109

Basic UDI-DI: 403276700000000001C11TR

in folgenden Varianten
in the following variants

Varianten / *Variants:*

1C11	1C11=L27-5-P/4N	1C11=N2425-5-P-OB	1C11=R24-5-P/15N
1C11=L22-1-P/15S	1C11=L27-6-P/15N	1C11=N2425-5-P/0	1C11=R24-5-P/4N
1C11=L22-1-P/4S	1C11=L27-6-P/4N	1C11=N2425-5-P/0-S	1C11=R25-1-P/15N
1C11=L22-2-P/15S	1C11=L28-2-P/15N	1C11=N2628-2-P-OB	1C11=R25-1-P/4N
1C11=L22-2-P/4S	1C11=L28-2-P/4N	1C11=N2628-2-P/0	1C11=R25-2-P/15N
1C11=L22-3-P/15S	1C11=L28-3-P/15N	1C11=N2628-2-P/0-S	1C11=R25-2-P/4N
1C11=L22-3-P/4S	1C11=L28-3-P/4N	1C11=N2628-3-P-OB	1C11=R25-3-P/15N
1C11=L23-1-P/15S	1C11=L28-4-P/15N	1C11=N2628-3-P/0	1C11=R25-3-P/4N
1C11=L23-1-P/4S	1C11=L28-4-P/4N	1C11=N2628-3-P/0-S	1C11=R25-4-P/15N
1C11=L23-2-P/15S	1C11=L28-5-P/15N	1C11=N2628-4-P-OB	1C11=R25-4-P/4N
1C11=L23-2-P/4S	1C11=L28-5-P/4N	1C11=N2628-4-P/0	1C11=R25-5-P/15N
1C11=L23-3-P/15S	1C11=L28-6-P/15N	1C11=N2628-4-P/0-S	1C11=R25-5-P/4N
1C11=L23-3-P/4S	1C11=L28-6-P/4N	1C11=N2628-5-P-OB	1C11=R26-2-P/15N
1C11=L24-1-P/15N	1C11=L29-3-P/15N	1C11=N2628-5-P/0	1C11=R26-2-P/4N
1C11=L24-1-P/4N	1C11=L29-3-P/4N	1C11=N2628-5-P/0-S	1C11=R26-3-P/15N
1C11=L24-2-P/15N	1C11=L29-4-P/15N	1C11=N2628-6-P-OB	1C11=R26-3-P/4N
1C11=L24-2-P/4N	1C11=L29-4-P/4N	1C11=N2628-6-P/0	1C11=R26-4-P/15N
1C11=L24-3-P/15N	1C11=L29-5-P/15N	1C11=N2628-6-P/0-S	1C11=R26-4-P/4N
1C11=L24-3-P/4N	1C11=L29-5-P/4N	1C11=N2930-3-P-OB	1C11=R26-5-P/15N
1C11=L24-4-P/15N	1C11=L29-6-P/15N	1C11=N2930-3-P/0	1C11=R26-5-P/4N
1C11=L24-4-P/4N	1C11=L29-6-P/4N	1C11=N2930-3-P/0-S	1C11=R26-6-P/15N
1C11=L24-5-P/15N	1C11=L30-3-P/15N	1C11=N2930-4-P-OB	1C11=R26-6-P/4N
1C11=L24-5-P/4N	1C11=L30-3-P/4N	1C11=N2930-4-P/0	1C11=R27-2-P/15N

1C11=L25-1-P/15N	1C11=L30-4-P/15N	1C11=N2930-4-P/0-S	1C11=R27-2-P/4N
1C11=L25-1-P/4N	1C11=L30-4-P/4N	1C11=N2930-5-P-OB	1C11=R27-3-P/15N
1C11=L25-2-P/15N	1C11=L30-5-P/15N	1C11=N2930-5-P/0	1C11=R27-3-P/4N
1C11=L25-2-P/4N	1C11=L30-5-P/4N	1C11=N2930-5-P/0-S	1C11=R27-4-P/15N
1C11=L25-3-P/15N	1C11=L30-6-P/15N	1C11=N2930-6-P-OB	1C11=R27-4-P/4N
1C11=L25-3-P/4N	1C11=L30-6-P/4N	1C11=N2930-6-P/0	1C11=R27-5-P/15N
1C11=L25-4-P/15N	1C11=N2223-1-P-OB	1C11=N2930-6-P/0-S	1C11=R27-5-P/4N
1C11=L25-4-P/4N	1C11=N2223-1-P/0	1C11=R22-1-P/15S	1C11=R27-6-P/15N
1C11=L25-5-P/15N	1C11=N2223-1-P/0-S	1C11=R22-1-P/4S	1C11=R27-6-P/4N
1C11=L25-5-P/4N	1C11=N2223-2-P-OB	1C11=R22-2-P/15S	1C11=R28-2-P/15N
1C11=L26-2-P/15N	1C11=N2223-2-P/0	1C11=R22-2-P/4S	1C11=R28-2-P/4N
1C11=L26-2-P/4N	1C11=N2223-2-P/0-S	1C11=R22-3-P/15S	1C11=R28-3-P/15N
1C11=L26-3-P/15N	1C11=N2223-3-P-OB	1C11=R22-3-P/4S	1C11=R28-3-P/4N
1C11=L26-3-P/4N	1C11=N2223-3-P/0	1C11=R23-1-P/15S	1C11=R28-4-P/15N
1C11=L26-4-P/15N	1C11=N2223-3-P/0-S	1C11=R23-1-P/4S	1C11=R28-4-P/4N
1C11=L26-4-P/4N	1C11=N2425-1-P-OB	1C11=R23-2-P/15S	1C11=R28-5-P/15N
1C11=L26-5-P/15N	1C11=N2425-1-P/0	1C11=R23-2-P/4S	1C11=R28-5-P/4N
1C11=L26-5-P/4N	1C11=N2425-1-P/0-S	1C11=R23-3-P/15S	1C11=R28-6-P/15N
1C11=L26-6-P/15N	1C11=N2425-2-P-OB	1C11=R23-3-P/4S	1C11=R28-6-P/4N
1C11=L26-6-P/4N	1C11=N2425-2-P/0	1C11=R24-1-P/15N	1C11=R29-3-P/15N
1C11=L27-2-P/15N	1C11=N2425-2-P/0-S	1C11=R24-1-P/4N	1C11=R29-3-P/4N
1C11=L27-2-P/4N	1C11=N2425-3-P-OB	1C11=R24-2-P/15N	1C11=R29-4-P/15N
1C11=L27-3-P/15N	1C11=N2425-3-P/0	1C11=R24-2-P/4N	1C11=R29-4-P/4N
1C11=L27-3-P/4N	1C11=N2425-3-P/0-S	1C11=R24-3-P/15N	1C11=R29-5-P/15N
1C11=L27-4-P/15N	1C11=N2425-4-P-OB	1C11=R24-3-P/4N	1C11=R29-5-P/4N
1C11=L27-4-P/4N	1C11=N2425-4-P/0	1C11=R24-4-P/15N	1C11=R29-6-P/15N
1C11=L27-5-P/15N	1C11=N2425-4-P/0-S	1C11=R24-4-P/4N	1C11=R29-6-P/4N
1C11=R30-3-P/15N	1C11=R30-4-P/15N	1C11=R30-5-P/15N	1C11=R30-6-P/15N
1C11=R30-3-P/4N	1C11=R30-4-P/4N	1C11=R30-5-P/4N	1C11=R30-6-P/4N

mit den Bestimmungen der nachstehenden EU-Verordnung(en), EU-Richtlinie(n) und Gemeinsame Spezifikationen übereinstimmt.

is in conformity with the relevant provisions of below-mentioned EC-Regulation(s), EC Directive(s) and Common Specifications.

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

Benannte Stelle / *Notified Body*: **N/A**

Benannte Stelle Adresse / *NB address*:

Benannte Stelle Nr. / *NB no.*:

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.

Common Specifications:
N/A

Die letzten beiden Ziffern des Jahres, in dem die CE-Kennzeichnung erstmalig angebracht wurde:
The last two characters of the year in which the CE marking was first affixed:

N/A

Gültig bis / *Valid through:*

N/A

Diese Erklärung gilt für alle Exemplare, die nach den entsprechenden Fertigungsunterlagen hergestellt wurden.

This declaration is valid for all products of the above design that are fabricated according to the respective fabrication documents.

Duderstadt, 2020-05-26

Ort, Datum / *Place, Date*



Unterschrift, Dr. Andreas Goppelt

Technischer Direktor /
Chief Technologie Officer (CTO)



Unterschrift, Dominik Schmidt

Für die Einhaltung der Regulierungsvorschriften
verantwortliche Person / Person Responsible for Regulatory
Compliance - Artikel 15, 2017/745 EU