

EU Declaration of Conformity

Manufacturer

Otto Bock HealthCare, LP
3820 West Great Lakes Drive
Salt Lake City , Utah 84120-7205
USA

SRN: N/A

Authorised Representative

Ottobock SE & Co. KGaA
Max-Näder-Straße 15
D-37115 Duderstadt, Germany

SRN: N/A

The signatory, who represents the below-mentioned manufacturer,

Manufacturer

Otto Bock HealthCare, LP
3820 West Great Lakes Drive
Salt Lake City , Utah 84120-7205
USA

herewith declares under his sole responsibility that the product

Product

Uneo Family of Liners:

- 6Y510 Uneo Flex
- 6Y512 Uneo 3D
- 6Y520 Uneo
- 6Y522 Uneo Tapered
- 6Y523 Uneo Skinguard
- 6Y4** Uneo Unique

Risk class I
according to Regulation (EU) 2017/745

Basic UDI-DI:
6Y510: 4064409000000006Y510ZT
6Y512: 4064409000000006Y51222
6Y520: 4064409000000006Y520ZW

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6Y522: 40644090000000006Y52225
6Y523: 40644090000000006Y52327
6Y400: 40644090000000006Y400ZK
6Y402: 40644090000000006Y402ZP
6Y404: 40644090000000006Y404ZT
6Y416: 40644090000000006Y41625
6Y417: 40644090000000006Y41727
6Y418: 40644090000000006Y41829
6Y430: 40644090000000006Y430ZU
6Y432: 40644090000000006Y43223
6Y434: 40644090000000006Y43427
6Y470: 40644090000000006Y4702B
616S132: 40644090000000616S1323V
616S134: 40644090000000616S1343Z
451F20: 40644090000000451F20V6

in the following variants

Variants

Uneo Flex	6Y510=175X75
Uneo Flex	6Y510=175X75-5
Uneo Flex	6Y510=175X75-7
Uneo Flex	6Y510=175X75-9
Uneo Flex	6Y510=175X75-G
Uneo Flex	6Y510=200X75
Uneo Flex	6Y510=200X75-5
Uneo Flex	6Y510=200X75-5-A
Uneo Flex	6Y510=200X75-7
Uneo Flex	6Y510=200X75-9
Uneo Flex	6Y510=200X75-A
Uneo Flex	6Y510=200X75-G
Uneo Flex	6Y510=210X125
Uneo Flex	6Y510=210X125-5
Uneo Flex	6Y510=210X125-5-A
Uneo Flex	6Y510=210X125-7
Uneo Flex	6Y510=210X125-9
Uneo Flex	6Y510=210X125-A
Uneo Flex	6Y510=210X125-G
Uneo Flex	6Y510=210X175

Uneo Flex	6Y510=210X175-5
Uneo Flex	6Y510=210X175-5-A
Uneo Flex	6Y510=210X175-7
Uneo Flex	6Y510=210X175-9
Uneo Flex	6Y510=210X175-A
Uneo Flex	6Y510=210X175-G
Uneo Flex	6Y510=225X75
Uneo Flex	6Y510=225X75-5
Uneo Flex	6Y510=225X75-5-A
Uneo Flex	6Y510=225X75-7
Uneo Flex	6Y510=225X75-9
Uneo Flex	6Y510=225X75-A
Uneo Flex	6Y510=225X75-G
Uneo Flex	6Y510=235X125
Uneo Flex	6Y510=235X125-5
Uneo Flex	6Y510=235X125-5-A
Uneo Flex	6Y510=235X125-7
Uneo Flex	6Y510=235X125-9
Uneo Flex	6Y510=235X125-A
Uneo Flex	6Y510=235X125-G
Uneo Flex	6Y510=235X175
Uneo Flex	6Y510=235X175-5
Uneo Flex	6Y510=235X175-5-A
Uneo Flex	6Y510=235X175-7
Uneo Flex	6Y510=235X175-9
Uneo Flex	6Y510=235X175-A
Uneo Flex	6Y510=235X175-G
Uneo Flex	6Y510=250X75
Uneo Flex	6Y510=250X75-5
Uneo Flex	6Y510=250X75-5-A
Uneo Flex	6Y510=250X75-7
Uneo Flex	6Y510=250X75-9
Uneo Flex	6Y510=250X75-A
Uneo Flex	6Y510=250X75-G
Uneo Flex	6Y510=260X125
Uneo Flex	6Y510=260X125-5
Uneo Flex	6Y510=260X125-5-A
Uneo Flex	6Y510=260X125-7
Uneo Flex	6Y510=260X125-9
Uneo Flex	6Y510=260X125-A
Uneo Flex	6Y510=260X125-G
Uneo Flex	6Y510=260X175
Uneo Flex	6Y510=260X175-5
Uneo Flex	6Y510=260X175-5-A

Uneo Flex	6Y510=260X175-7
Uneo Flex	6Y510=260X175-9
Uneo Flex	6Y510=260X175-A
Uneo Flex	6Y510=260X175-G
Uneo Flex	6Y510=275X75
Uneo Flex	6Y510=275X75-5
Uneo Flex	6Y510=275X75-5-A
Uneo Flex	6Y510=275X75-7
Uneo Flex	6Y510=275X75-9
Uneo Flex	6Y510=275X75-A
Uneo Flex	6Y510=275X75-G
Uneo Flex	6Y510=285X125
Uneo Flex	6Y510=285X125-5
Uneo Flex	6Y510=285X125-5-A
Uneo Flex	6Y510=285X125-7
Uneo Flex	6Y510=285X125-9
Uneo Flex	6Y510=285X125-A
Uneo Flex	6Y510=285X125-G
Uneo Flex	6Y510=285X175
Uneo Flex	6Y510=285X175-5
Uneo Flex	6Y510=285X175-5-A
Uneo Flex	6Y510=285X175-7
Uneo Flex	6Y510=285X175-9
Uneo Flex	6Y510=285X175-A
Uneo Flex	6Y510=285X175-G
Uneo Flex	6Y510=300X75
Uneo Flex	6Y510=300X75-5
Uneo Flex	6Y510=300X75-5-A
Uneo Flex	6Y510=300X75-7
Uneo Flex	6Y510=300X75-9
Uneo Flex	6Y510=300X75-A
Uneo Flex	6Y510=300X75-G
Uneo Flex	6Y510=310X125
Uneo Flex	6Y510=310X125-5
Uneo Flex	6Y510=310X125-5-A
Uneo Flex	6Y510=310X125-7
Uneo Flex	6Y510=310X125-9
Uneo Flex	6Y510=310X125-A
Uneo Flex	6Y510=310X125-G
Uneo Flex	6Y510=310X175
Uneo Flex	6Y510=310X175-5
Uneo Flex	6Y510=310X175-5-A
Uneo Flex	6Y510=310X175-7
Uneo Flex	6Y510=310X175-9

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Uneo Flex	6Y510=310X175-A
Uneo Flex	6Y510=310X175-G
Uneo Flex	6Y510=325X75
Uneo Flex	6Y510=325X75-5
Uneo Flex	6Y510=325X75-5-A
Uneo Flex	6Y510=325X75-7
Uneo Flex	6Y510=325X75-9
Uneo Flex	6Y510=325X75-A
Uneo Flex	6Y510=325X75-G
Uneo Flex	6Y510=SPECIAL
Uneo Flex	6Y510=SPECIAL-A
Uneo 3D	6Y512=1_K
Uneo 3D	6Y512=2_K
Uneo 3D	6Y512=210X125
Uneo 3D	6Y512=210X125-F
Uneo 3D	6Y512=210X125-F-G
Uneo Fresh	6Y512=210X125-F-P
Uneo 3D	6Y512=210X125-G
Uneo Fresh	6Y512=210X125-P
Uneo 3D	6Y512=210X175
Uneo 3D	6Y512=210X175-F
Uneo 3D	6Y512=210X175-F-G
Uneo Fresh	6Y512=210X175-F-P
Uneo 3D	6Y512=210X175-G
Uneo Fresh	6Y512=210X175-P
Uneo 3D	6Y512=235X125
Uneo 3D	6Y512=235X125-F
Uneo 3D	6Y512=235X125-F-G
Uneo Fresh	6Y512=235X125-F-P
Uneo 3D	6Y512=235X125-G
Uneo Fresh	6Y512=235X125-P
Uneo 3D	6Y512=235X175
Uneo 3D	6Y512=235X175-F
Uneo 3D	6Y512=235X175-F-G
Uneo Fresh	6Y512=235X175-F-P
Uneo 3D	6Y512=235X175-G
Uneo Fresh	6Y512=235X175-P
Uneo 3D	6Y512=250X75
Uneo 3D	6Y512=250X75-F
Uneo 3D	6Y512=250X75-F-G
Uneo Fresh	6Y512=250X75-F-P
Uneo 3D	6Y512=250X75-G
Uneo Fresh	6Y512=250X75-P

Uneo 3D	6Y512=265X125
Uneo 3D	6Y512=265X125-F
Uneo 3D	6Y512=265X125-F-G
Uneo Fresh	6Y512=265X125-F-P
Uneo 3D	6Y512=265X125-G
Uneo Fresh	6Y512=265X125-P
Uneo 3D	6Y512=265X175
Uneo 3D	6Y512=265X175-F
Uneo 3D	6Y512=265X175-F-G
Uneo Fresh	6Y512=265X175-F-P
Uneo 3D	6Y512=265X175-G
Uneo Fresh	6Y512=265X175-P
Uneo 3D	6Y512=280X125
Uneo 3D	6Y512=280X125-F
Uneo 3D	6Y512=280X125-F-G
Uneo Fresh	6Y512=280X125-F-P
Uneo 3D	6Y512=280X125-G
Uneo Fresh	6Y512=280X125-P
Uneo 3D	6Y512=280X175
Uneo 3D	6Y512=280X175-F
Uneo 3D	6Y512=280X175-F-G
Uneo Fresh	6Y512=280X175-F-P
Uneo 3D	6Y512=280X175-G
Uneo Fresh	6Y512=280X175-P
Uneo 3D	6Y512=300X125
Uneo 3D	6Y512=300X125-F
Uneo 3D	6Y512=300X125-F-G
Uneo Fresh	6Y512=300X125-F-P
Uneo 3D	6Y512=300X125-G
Uneo Fresh	6Y512=300X125-P
Uneo 3D	6Y512=300X175
Uneo 3D	6Y512=300X175-F
Uneo 3D	6Y512=300X175-F-G
Uneo Fresh	6Y512=300X175-F-P
Uneo 3D	6Y512=300X175-G
Uneo Fresh	6Y512=300X175-P
Uneo	6Y520=190
Uneo	6Y520=190-5
Uneo	6Y520=190-5-A
Uneo	6Y520=190-7
Uneo	6Y520=190-9
Uneo	6Y520=190-A
Uneo	6Y520=230

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Uneo	6Y520=230-5
Uneo	6Y520=230-5-A
Uneo	6Y520=230-7
Uneo	6Y520=230-9
Uneo	6Y520=230-A
Uneo	6Y520=290
Uneo	6Y520=290-5
Uneo	6Y520=290-5-A
Uneo	6Y520=290-7
Uneo	6Y520=290-9
Uneo	6Y520=290-A
Uneo	6Y520=330
Uneo	6Y520=330-5
Uneo	6Y520=330-5-A
Uneo	6Y520=330-7
Uneo	6Y520=330-9
Uneo	6Y520=330-A
Uneo	6Y520=400
Uneo	6Y520=400-5
Uneo	6Y520=400-5-A
Uneo	6Y520=400-7
Uneo	6Y520=400-9
Uneo	6Y520=400-A
Uneo	6Y520=SPECIAL
Uneo	6Y520=SPECIAL-A
Uneo	6Y522=190
Uneo	6Y522=190-A
Uneo Skinguard	6Y522=190-G
Uneo	6Y522=210
Uneo	6Y522=210-A
Uneo Skinguard	6Y522=210-G
Uneo	6Y522=230
Uneo	6Y522=230-A
Uneo Skinguard	6Y522=230-G
Uneo	6Y522=250
Uneo	6Y522=250-A
Uneo Skinguard	6Y522=250-G
Uneo	6Y522=290
Uneo	6Y522=290-A
Uneo Skinguard	6Y522=290-G
Uneo	6Y522=310
Uneo	6Y522=310-A
Uneo Skinguard	6Y522=310-G

Uneo	6Y523=190
Uneo	6Y523=190-A
Uneo Skinguard	6Y523=190-G
Uneo	6Y523=210
Uneo	6Y523=210-A
Uneo Skinguard	6Y523=210-G
Uneo	6Y523=230
Uneo	6Y523=230-A
Uneo Skinguard	6Y523=230-G
Uneo	6Y523=250
Uneo	6Y523=250-A
Uneo Skinguard	6Y523=250-G
Uneo	6Y523=290
Uneo	6Y523=290-A
Uneo Skinguard	6Y523=290-G
Uneo	6Y523=310
Uneo	6Y523=310-A
Uneo Skinguard	6Y523=310-G

Uneo Unique BK Standard - NEW	6Y400
Uneo Unique BK Standard - REPLACEMENT	6Y402
Uneo Unique BK Standard-ALTERATION	6Y404
Uneo Unique BK Shapeplus-NEW	6Y416
Uneo Unique BK Shapeplus-REPLACEMENT	6Y417
Uneo Unique BK Shapeplus-ALTERATION	6Y418
Uneo Unique AK Standard-NEW	6Y430
Uneo Unique AK Standard-REPLACEMENT	6Y432
Uneo Unique AK Standard-ALTERATION	6Y434
Custom Spot	6Y470
Fit Kit #1 (Liners)	451F20=1
Fit Kit #2 (Liners)	451F20=2
Sticky Spots, Size 1	616S132=1
Sticky Spots, Size 2	616S132=2
Sticky Spots, Size 3	616S132=3
Sticky Spots, Size 4	616S132=4
Sticky Spots, Size 5	616S132=5
Spots, Size 1	616S134=1
Spots, Size 2	616S134=2
Spots, Size 3	616S134=3
Spots, Size 4	616S134=4
Spots, Size 5	616S134=5

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

2017/745 EU Regulation of the European Parliament and of the Council on medical devices

The conformity is declared based on Article 52(7), Annex II and III of the Regulation (EU) 2017/745.

Salt Lake City, Utah USA,

11 Jun 2020

Place, Date



Dave J. Wall
COO North America



Caleb Beck
Director, Regulatory & Quality Compliance
North America

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