

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

1E95 Challenger

Risk class I
according to Regulation (EU) 2017/745
Basic UDI-DI: 406440900000000001E95SM

in the following variants

Variants

1E95 Challenger	1E95=N2324-2-P/0
1E95 Test Foot	1E95=N2324-2-P-OB
Challenger Service Foot	1E95=N2324-2-P-S
1E95 Challenger	1E95=N2526-2-P/0
1E95 Test Foot	1E95=N2526-2-P-OB
Challenger Service Foot	1E95=N2526-2-P-S
1E95 Challenger	1E95=N2526-3-P/0

1E95 Test Foot	1E95=N2526-3-P-OB
Challenger Service Foot	1E95=N2526-3-P-S
1E95 Challenger	1E95=N2526-4-P/0
1E95 Test foot	1E95=N2526-4-P-OB
Challenger Service Foot	1E95=N2526-4-P-S
1E95 Challenger	1E95=N2728-2-P/0
1E95 Test Foot	1E95=N2728-2-P-OB
Challenger Service Foot	1E95=N2728-2-P-S
1E95 Challenger	1E95=N2728-3-P/0
1E95 Test Foot	1E95=N2728-3-P-OB
Challenger Service Foot	1E95=N2728-3-P-S
1E95 Challenger	1E95=N2728-4-P/0
1E95 Test foot	1E95=N2728-4-P-OB
Challenger Service Foot	1E95=N2728-4-P-S
1E95 Challenger	1E95=N2930-3-P/0
1E95 Test Foot	1E95=N2930-3-P-OB
Challenger Service Foot	1E95=N2930-3-P-S
1E95 Challenger	1E95=N2930-4-P/0
1E95 Test foot	1E95=N2930-4-P-OB
Challenger Service Foot	1E95=N2930-4-P-S

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