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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

1C30 Trias

Risk class I according to Regulation (EU) 2017/745
Basic UDI-DI: 40644090000000001C30RF

in the following variants

Variants

1C30=N21-1-P/0
Trial Foot 1C30 without Footshell
1C30=N21-1-P/0-A
1C30 Trial Foot without Footshell
1C30=N21-1-P/0-OB
1C30 without Footshell
1C30=N21-2-P/0
Trial Foot 1C30 without Footshell
1C30=N21-2-P/0-A
1C30 Trial Foot without Footshell
1C30=N21-2-P/0-OB

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1C30 without Footshell	1C30=N22-1-P/0
Trial Foot 1C30 without Footshell	1C30=N22-1-P/0-A
1C30 Trial Foot without Footshell	1C30=N22-1-P/0-OB
1C30 without Footshell	1C30=N22-2-P/0
Trial Foot 1C30 without Footshell	1C30=N22-2-P/0-A
1C30 Trial Foot without Footshell	1C30=N22-2-P/0-OB
1C30 without Footshell	1C30=N23-1-P/0
Trial Foot 1C30 without Footshell	1C30=N23-1-P/0-A
1C30 Trial Foot without Footshell	1C30=N23-1-P/0-OB
1C30 without Footshell	1C30=N23-2-P/0
Trial Foot 1C30 without Footshell	1C30=N23-2-P/0-A
1C30 Trial Foot without Footshell	1C30=N23-2-P/0-OB
1C30 without Footshell	1C30=N23-3-P/0
Trial Foot 1C30 without Footshell	1C30=N23-3-P/0-A
1C30 Trial Foot without Footshell	1C30=N23-3-P/0-OB
1C30 without Footshell	1C30=N24-1-P/0
Trial Foot 1C30 without Footshell	1C30=N24-1-P/0-A
1C30 Trial Foot without Footshell	1C30=N24-1-P/0-OB
1C30 without Footshell	1C30=N24-2-P/0
Trial Foot 1C30 without Footshell	1C30=N24-2-P/0-A
1C30 Trial Foot without Footshell	1C30=N24-2-P/0-OB
1C30 without Footshell	1C30=N24-3-P/0
Trial Foot 1C30 without Footshell	1C30=N24-3-P/0-A
1C30 Trial Foot without Footshell	1C30=N24-3-P/0-OB
1C30 without Footshell	1C30=N25-1-P/0
Trial Foot 1C30 without Footshell	1C30=N25-1-P/0-A
1C30 Trial Foot without Footshell	1C30=N25-1-P/0-OB
1C30 without Footshell	1C30=N25-2-P/0
Trial Foot 1C30 without Footshell	1C30=N25-2-P/0-A
1C30 Trial Foot without Footshell	1C30=N25-2-P/0-OB
1C30 without Footshell	1C30=N25-3-P/0
Trial Foot 1C30 without Footshell	1C30=N25-3-P/0-A
1C30 Trial Foot without Footshell	1C30=N25-3-P/0-OB
1C30 without Footshell	1C30=N26-1-P/0
Trial Foot 1C30 without Footshell	1C30=N26-1-P/0-A
1C30 Trial Foot without Footshell	1C30=N26-1-P/0-OB
1C30 without Footshell	1C30=N26-2-P/0
Trial Foot 1C30 without Footshell	1C30=N26-2-P/0-A
1C30 Trial Foot without Footshell	1C30=N26-2-P/0-OB
1C30 without Footshell	1C30=N26-3-P/0
1C30 without Footshell	1C30=N26-3-P/0-A
1C30 Trial Foot without Footshell	1C30=N26-3-P/0-OB
1C30 without Footshell	1C30=N27-1-P/0
Trial Foot 1C30 without Footshell	1C30=N27-1-P/0-A
1C30 Trial Foot without Footshell	1C30=N27-1-P/0-OB
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	1C30 without Footshell	1C30=N27-2-P/0
l	Trial Foot 1C30 without Footshell	1C30=N27-2-P/0-A
	1C30 Trial Foot without Footshell	1C30=N27-2-P/0-OB
	1C30 without Footshell	1C30=N27-3-P/0
	Trial Foot 1C30 without Footshell	1C30=N27-3-P/0-A
	1C30 Trial Foot without Footshell	1C30=N27-3-P/0-OB
l	1C30 without Footshell	1C30=N27-4-P/0
l	Trial Foot 1C30 without Footshell	1C30=N27-4-P/0-A
	1C30 Trial Foot without Footshell	1C30=N27-4-P/0-OB
	1C30 without Footshell	1C30=N28-1-P/0
	Trial Foot 1C30 without Footshell	1C30=N28-1-P/0-A
	1C30 Trial Foot without Footshell	1C30=N28-1-P/0-OB
	1C30 without Footshell	1C30=N28-2-P/0
	Trial Foot 1C30 without Footshell	1C30=N28-2-P/0-A
	1C30 Trial Foot without Footshell	1C30=N28-2-P/0-OB
	1C30 without Footshell	1C30=N28-3-P/0
	Trial Foot 1C30 without Footshell	1C30=N28-3-P/0-A
	1C30 Trial Foot without Footshell	1C30=N28-3-P/0-OB
	1C30 Without Footshell	1C30=N28-3-P/0-S
	1C30 without Footshell	1C30=N28-4-P/0
-	Trial Foot 1C30 without Footshell	1C30=N28-4-P/0-A
l	1C30 Trial Foot without Footshell	1C30=N28-4-P/0-OB
l	1C30 without Footshell	1C30=N29-1-P/0
	Trial Foot 1C30 without Footshell	1C30=N29-1-P/0-A
	1C30 Trial Foot without Footshell	1C30=N29-1-P/0-OB
	1C30 without Footshell	1C30=N29-2-P/0
	Trial Foot 1C30 without Footshell	1C30=N29-2-P/0-A
	1C30 Trial Foot without Footshell	1C30=N29-2-P/0-OB
	1C30 without Footshell	1C30=N29-3-P/0
	Trial Foot 1C30 without Footshell	1C30=N29-3-P/0-A
	1C30 Trial Foot without Footshell	1C30=N29-3-P/0-OB
	1C30 without Footshell	1C30=N30-1-P/0
	Trial Foot 1C30 without Footshell	1C30=N30-1-P/0-A
l	1C30 Trial Foot without Footshell	1C30=N30-1-P/0-OB
l	1C30 without Footshell	1C30=N30-2-P/0
	Trial Foot 1C30 without Footshell	1C30=N30-2-P/0-A
	1C30 Trial Foot without Footshell	1C30=N30-2-P/0-OB
	1C30 without Footshell	1C30=N30-3-P/0
	Trial Foot 1C30 without Footshell	1C30=N30-3-P/0-A
	1C30 Trial Foot without Footshell	1C30=N30-3-P/0-OB



Jun 2020

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,

Place, Date

Caleb Beck

Director, Regulatory & Quality Compliance

North America

Dave J. Wall

COO North America