

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

1C62 Triton H

Risk class I
according to Regulation (EU) 2017/745
Basic UDI-DI: 406440900000000001C62RU

in the following variants

Variants

1C62 Triton H	1C62
1C62 Triton H, L, without footshell	1C62=L21-1-0-P/0
1C62 Triton H, L, without footshell	1C62=L21-1-1-P/0
1C62 Trial Foot, L, Without Footshell	1C62=L21-1-P/0-OB
1C62 Trial Service Foot	1C62=L21-1-P/0-S
1C62 Triton H, L, without footshell	1C62=L21-2-2-P/0
1C62 Triton H, L, without footshell	1C62=L21-2-3-P/0

1C62 Trial Foot, L, Without Footshell	1C62=L21-2-P/0-OB
1C62 Trial Service Foot	1C62=L21-2-P/0-S
1C62 Triton H, L, without footshell	1C62=L21-3-4-P/0
1C62 Triton H, L, without footshell	1C62=L21-3-5-P/0
1C62 Trial Foot, L, Without Footshell	1C62=L21-3-P/0-OB
1C62 Trial Service Foot	1C62=L21-3-P/0-S
1C62 Triton H, L, without footshell	1C62=L22-1-0-P/0
1C62 Triton H, L, without footshell	1C62=L22-1-1-P/0
1C62 Trial Foot, L, Without Footshell	1C62=L22-1-P/0-OB
1C62 Trial Service Foot	1C62=L22-1-P/0-S
1C62 Triton H, L, without footshell	1C62=L22-2-2-P/0
1C62 Triton H, L, without footshell	1C62=L22-2-3-P/0
1C62 Trial Foot, L, Without Footshell	1C62=L22-2-P/0-OB
1C62 Trial Service Foot	1C62=L22-2-P/0-S
1C62 Triton H, L, without footshell	1C62=L22-3-4-P/0
1C62 Triton H, L, without footshell	1C62=L22-3-5-P/0
1C62 Trial Foot, L, Without Footshell	1C62=L22-3-P/0-OB
1C62 Trial Service Foot	1C62=L22-3-P/0-S
1C62 Triton H, L, without footshell	1C62=L23-1-0-P/0
1C62 Triton H, L, without footshell	1C62=L23-1-1-P/0
1C62 Trial Foot, L, Without Footshell	1C62=L23-1-P/0-OB
1C62 Trial Service Foot	1C62=L23-1-P/0-S
1C62 Triton H, L, without footshell	1C62=L23-2-2-P/0
1C62 Triton H, L, without footshell	1C62=L23-2-3-P/0
1C62 Trial Foot, L, Without Footshell	1C62=L23-2-P/0-OB
1C62 Trial Service Foot	1C62=L23-2-P/0-S
1C62 Triton H, L, without footshell	1C62=L23-3-4-P/0
1C62 Triton H, L, without footshell	1C62=L23-3-5-P/0
1C62 Trial Foot, L, Without Footshell	1C62=L23-3-P/0-OB
1C62 Trial Service Foot	1C62=L23-3-P/0-S
1C62 Triton H, L, without footshell	1C62=L24-1-0-P/0
1C62 Triton H, L, without footshell	1C62=L24-1-1-P/0
1C62 Trial Foot, L, Without Footshell	1C62=L24-1-P/0-OB
1C62 Trial Service Foot	1C62=L24-1-P/0-S
1C62 Triton H, L, without footshell	1C62=L24-2-2-P/0
1C62 Triton H, L, without footshell	1C62=L24-2-3-P/0
1C62 Trial Foot, L, Without Footshell	1C62=L24-2-P/0-OB
1C62 Trial Service Foot	1C62=L24-2-P/0-S
1C62 Triton H, L, without footshell	1C62=L24-3-4-P/0
1C62 Triton H, L, without footshell	1C62=L24-3-5-P/0
1C62 Trial Foot, L, Without Footshell	1C62=L24-3-P/0-OB
1C62 Trial Service Foot	1C62=L24-3-P/0-S
1C62 Triton H, L, without footshell	1C62=L25-1-0-P/0
1C62 Triton H, L, without footshell	1C62=L25-1-1-P/0
1C62 Trial Foot, L, Without Footshell	1C62=L25-1-P/0-OB

1C62 Trial Service Foot	1C62=L25-1-P/0-S
1C62 Triton H, L, without footshell	1C62=L25-2-2-P/0
1C62 Triton H, L, without footshell	1C62=L25-2-3-P/0
1C62 Trial Foot, L, Without Footshell	1C62=L25-2-P/0-OB
1C62 Trial Service Foot	1C62=L25-2-P/0-S
1C62 Triton H, L, without footshell	1C62=L25-3-4-P/0
1C62 Triton H, L, without footshell	1C62=L25-3-5-P/0
1C62 Trial Foot, L, Without Footshell	1C62=L25-3-P/0-OB
1C62 Trial Service Foot	1C62=L25-3-P/0-S
1C62 Triton H, L, without footshell	1C62=L25-4-6-P/0
1C62 Triton H, L, without footshell	1C62=L25-4-7-P/0
1C62 Trial Foot, L, Without Footshell	1C62=L25-4-P/0-OB
1C62 Trial Service Foot	1C62=L25-4-P/0-S
1C62 Triton H, L, without footshell	1C62=L25-5-8-P/0
1C62 Triton H, L, without footshell	1C62=L25-5-9-P/0
1C62 Trial Foot, L, Without Footshell	1C62=L25-5-P/0-OB
1C62 Trial Service Foot	1C62=L25-5-P/0-S
1C62 Triton H, L, without footshell	1C62=L26-1-0-P/0
1C62 Triton H, L, without footshell	1C62=L26-1-1-P/0
1C62 Trial Foot, L, Without Footshell	1C62=L26-1-P/0-OB
1C62 Trial Service Foot	1C62=L26-1-P/0-S
1C62 Triton H, L, without footshell	1C62=L26-2-2-P/0
1C62 Triton H, L, without footshell	1C62=L26-2-3-P/0
1C62 Trial Foot, L, Without Footshell	1C62=L26-2-P/0-OB
1C62 Trial Service Foot	1C62=L26-2-P/0-S
1C62 Triton H, L, without footshell	1C62=L26-3-4-P/0
1C62 Triton H, L, without footshell	1C62=L26-3-5-P/0
1C62 Trial Foot, L, Without Footshell	1C62=L26-3-P/0-OB
1C62 Trial Service Foot	1C62=L26-3-P/0-S
1C62 Triton H, L, without footshell	1C62=L26-4-6-P/0
1C62 Triton H, L, without footshell	1C62=L26-4-7-P/0
1C62 Trial Foot, L, Without Footshell	1C62=L26-4-P/0-OB
1C62 Trial Service Foot	1C62=L26-4-P/0-S
1C62 Triton H, L, without footshell	1C62=L26-5-8-P/0
1C62 Triton H, L, without footshell	1C62=L26-5-9-P/0
1C62 Trial Foot, L, Without Footshell	1C62=L26-5-P/0-OB
1C62 Trial Service Foot	1C62=L26-5-P/0-S
1C62 Triton H, L, without footshell	1C62=L27-2-2-P/0
1C62 Triton H, L, without footshell	1C62=L27-2-3-P/0
1C62 Trial Foot, L, Without Footshell	1C62=L27-2-P/0-OB
1C62 Trial Service Foot	1C62=L27-2-P/0-S
1C62 Triton H, L, without footshell	1C62=L27-3-4-P/0
1C62 Triton H, L, without footshell	1C62=L27-3-5-P/0
1C62 Trial Foot, L, Without Footshell	1C62=L27-3-P/0-OB
1C62 Trial Service Foot	1C62=L27-3-P/0-S

1C62 Triton H, L, without footshell	1C62=L27-4-6-P/0
1C62 Triton H, L, without footshell	1C62=L27-4-7-P/0
1C62 Trial Foot, L, Without Footshell	1C62=L27-4-P/0-OB
1C62 Trial Service Foot	1C62=L27-4-P/0-S
1C62 Triton H, L, without footshell	1C62=L27-5-8-P/0
1C62 Triton H, L, without footshell	1C62=L27-5-9-P/0
1C62 Trial Foot, L, Without Footshell	1C62=L27-5-P/0-OB
1C62 Trial Service Foot	1C62=L27-5-P/0-S
1C62 Triton H, L, without footshell	1C62=L28-2-2-P/0
1C62 Triton H, L, without footshell	1C62=L28-2-3-P/0
1C62 Trial Foot, L, Without Footshell	1C62=L28-2-P/0-OB
1C62 Trial Service Foot	1C62=L28-2-P/0-S
1C62 Triton H, L, without footshell	1C62=L28-3-4-P/0
1C62 Triton H, L, without footshell	1C62=L28-3-5-P/0
1C62 Trial Foot, L, Without Footshell	1C62=L28-3-P/0-OB
1C62 Trial Service Foot	1C62=L28-3-P/0-S
1C62 Triton H, L, without footshell	1C62=L28-4-6-P/0
1C62 Triton H, L, without footshell	1C62=L28-4-7-P/0
1C62 Trial Foot, L, Without Footshell	1C62=L28-4-P/0-OB
1C62 Trial Service Foot	1C62=L28-4-P/0-S
1C62 Triton H, L, without footshell	1C62=L28-5-8-P/0
1C62 Triton H, L, without footshell	1C62=L28-5-9-P/0
1C62 Trial Foot, L, Without Footshell	1C62=L28-5-P/0-OB
1C62 Trial Service Foot	1C62=L28-5-P/0-S
1C62 Triton H, L, without footshell	1C62=L29-2-2-P/0
1C62 Triton H, L, without footshell	1C62=L29-2-3-P/0
1C62 Trial Foot, L, Without Footshell	1C62=L29-2-P/0-OB
1C62 Trial Service Foot	1C62=L29-2-P/0-S
1C62 Triton H, L, without footshell	1C62=L29-3-4-P/0
1C62 Triton H, L, without footshell	1C62=L29-3-5-P/0
1C62 Trial Foot, L, Without Footshell	1C62=L29-3-P/0-OB
1C62 Trial Service Foot	1C62=L29-3-P/0-S
1C62 Triton H, L, without footshell	1C62=L29-4-6-P/0
1C62 Triton H, L, without footshell	1C62=L29-4-7-P/0
1C62 Trial Foot, L, Without Footshell	1C62=L29-4-P/0-OB
1C62 Trial Service Foot	1C62=L29-4-P/0-S
1C62 Triton H, L, without footshell	1C62=L29-5-8-P/0
1C62 Triton H, L, without footshell	1C62=L29-5-9-P/0
1C62 Trial Foot, L, Without Footshell	1C62=L29-5-P/0-OB
1C62 Trial Service Foot	1C62=L29-5-P/0-S
1C62 Triton H, L, without footshell	1C62=L30-2-2-P/0
1C62 Triton H, L, without footshell	1C62=L30-2-3-P/0
1C62 Trial Foot, L, Without Footshell	1C62=L30-2-P/0-OB
1C62 Trial Service Foot	1C62=L30-2-P/0-S
1C62 Triton H, L, without footshell	1C62=L30-3-4-P/0

1C62 Triton H, L, without footshell	1C62=L30-3-5-P/0
1C62 Trial Foot, L, Without Footshell	1C62=L30-3-P/0-OB
1C62 Trial Service Foot	1C62=L30-3-P/0-S
1C62 Triton H, L, without footshell	1C62=L30-4-6-P/0
1C62 Triton H, L, without footshell	1C62=L30-4-7-P/0
1C62 Trial Foot, L, Without Footshell	1C62=L30-4-P/0-OB
1C62 Trial Service Foot	1C62=L30-4-P/0-S
1C62 Triton H, L, without footshell	1C62=L30-5-8-P/0
1C62 Triton H, L, without footshell	1C62=L30-5-9-P/0
1C62 Trial Foot, L, Without Footshell	1C62=L30-5-P/0-OB
1C62 Trial Service Foot	1C62=L30-5-P/0-S
1C62 Triton H, R, without footshell	1C62=R21-1-0-P/0
1C62 Triton H, R, without footshell	1C62=R21-1-1-P/0
1C62 Trial Foot, R, Without Footshell	1C62=R21-1-P/0-OB
1C62 Trial Service Foot	1C62=R21-1-P/0-S
1C62 Triton H, R, without footshell	1C62=R21-2-2-P/0
1C62 Triton H, R, without footshell	1C62=R21-2-3-P/0
1C62 Trial Foot, R, Without Footshell	1C62=R21-2-P/0-OB
1C62 Trial Service Foot	1C62=R21-2-P/0-S
1C62 Triton H, R, without footshell	1C62=R21-3-4-P/0
1C62 Triton H, R, without footshell	1C62=R21-3-5-P/0
1C62 Trial Foot, R, Without Footshell	1C62=R21-3-P/0-OB
1C62 Trial Service Foot	1C62=R21-3-P/0-S
1C62 Triton H, R, without footshell	1C62=R22-1-0-P/0
1C62 Triton H, R, without footshell	1C62=R22-1-1-P/0
1C62 Trial Foot, R, Without Footshell	1C62=R22-1-P/0-OB
1C62 Trial Service Foot	1C62=R22-1-P/0-S
1C62 Triton H, R, without footshell	1C62=R22-2-2-P/0
1C62 Triton H, R, without footshell	1C62=R22-2-3-P/0
1C62 Trial Foot, R, Without Footshell	1C62=R22-2-P/0-OB
1C62 Trial Service Foot	1C62=R22-2-P/0-S
1C62 Triton H, R, without footshell	1C62=R22-3-4-P/0
1C62 Triton H, R, without footshell	1C62=R22-3-5-P/0
1C62 Trial Foot, R, Without Footshell	1C62=R22-3-P/0-OB
1C62 Trial Service Foot	1C62=R22-3-P/0-S
1C62 Triton H, R, without footshell	1C62=R23-1-0-P/0
1C62 Triton H, R, without footshell	1C62=R23-1-1-P/0
1C62 Trial Foot, R, Without Footshell	1C62=R23-1-P/0-OB
1C62 Trial Service Foot	1C62=R23-1-P/0-S
1C62 Triton H, R, without footshell	1C62=R23-2-2-P/0
1C62 Triton H, R, without footshell	1C62=R23-2-3-P/0
1C62 Trial Foot, R, Without Footshell	1C62=R23-2-P/0-OB
1C62 Trial Service Foot	1C62=R23-2-P/0-S
1C62 Triton H, R, without footshell	1C62=R23-3-4-P/0
1C62 Triton H, R, without footshell	1C62=R23-3-5-P/0

1C62 Trial Foot, R, Without Footshell	1C62=R23-3-P/0-OB
1C62 Trial Service Foot	1C62=R23-3-P/0-S
1C62 Triton H, R, without footshell	1C62=R24-1-0-P/0
1C62 Triton H, R, without footshell	1C62=R24-1-1-P/0
1C62 Trial Foot, R, Without Footshell	1C62=R24-1-P/0-OB
1C62 Trial Service Foot	1C62=R24-1-P/0-S
1C62 Triton H, R, without footshell	1C62=R24-2-2-P/0
1C62 Triton H, R, without footshell	1C62=R24-2-3-P/0
1C62 Trial Foot, R, Without Footshell	1C62=R24-2-P/0-OB
1C62 Trial Service Foot	1C62=R24-2-P/0-S
1C62 Triton H, R, without footshell	1C62=R24-3-4-P/0
1C62 Triton H, R, without footshell	1C62=R24-3-5-P/0
1C62 Trial Foot, R, Without Footshell	1C62=R24-3-P/0-OB
1C62 Trial Service Foot	1C62=R24-3-P/0-S
1C62 Triton H, R, without footshell	1C62=R25-1-0-P/0
1C62 Triton H, R, without footshell	1C62=R25-1-1-P/0
1C62 Trial Foot, R, Without Footshell	1C62=R25-1-P/0-OB
1C62 Trial Service Foot	1C62=R25-1-P/0-S
1C62 Triton H, R, without footshell	1C62=R25-2-2-P/0
1C62 Triton H, R, without footshell	1C62=R25-2-3-P/0
1C62 Trial Foot, R, Without Footshell	1C62=R25-2-P/0-OB
1C62 Trial Service Foot	1C62=R25-2-P/0-S
1C62 Triton H, R, without footshell	1C62=R25-3-4-P/0
1C62 Triton H, R, without footshell	1C62=R25-3-5-P/0
1C62 Trial Foot, R, Without Footshell	1C62=R25-3-P/0-OB
1C62 Trial Service Foot	1C62=R25-3-P/0-S
1C62 Triton H, R, without footshell	1C62=R25-4-6-P/0
1C62 Triton H, R, without footshell	1C62=R25-4-7-P/0
1C62 Trial Foot, R, Without Footshell	1C62=R25-4-P/0-OB
1C62 Trial Service Foot	1C62=R25-4-P/0-S
1C62 Triton H, R, without footshell	1C62=R25-5-8-P/0
1C62 Triton H, R, without footshell	1C62=R25-5-9-P/0
1C62 Trial Foot, R, Without Footshell	1C62=R25-5-P/0-OB
1C62 Trial Service Foot	1C62=R25-5-P/0-S
1C62 Triton H, R, without footshell	1C62=R26-1-0-P/0
1C62 Triton H, R, without footshell	1C62=R26-1-1-P/0
1C62 Trial Foot, R, Without Footshell	1C62=R26-1-P/0-OB
1C62 Trial Service Foot	1C62=R26-1-P/0-S
1C62 Triton H, R, without footshell	1C62=R26-2-2-P/0
1C62 Triton H, R, without footshell	1C62=R26-2-3-P/0
1C62 Trial Foot, R, Without Footshell	1C62=R26-2-P/0-OB
1C62 Trial Service Foot	1C62=R26-2-P/0-S
1C62 Triton H, R, without footshell	1C62=R26-3-4-P/0
1C62 Triton H, R, without footshell	1C62=R26-3-5-P/0
1C62 Trial Foot, R, Without Footshell	1C62=R26-3-P/0-OB

1C62 Trial Service Foot	1C62=R26-3-P/0-S
1C62 Triton H, R, without footshell	1C62=R26-4-6-P/0
1C62 Triton H, R, without footshell	1C62=R26-4-7-P/0
1C62 Trial Foot, R, Without Footshell	1C62=R26-4-P/0-OB
1C62 Trial Service Foot	1C62=R26-4-P/0-S
1C62 Triton H, R, without footshell	1C62=R26-5-8-P/0
1C62 Triton H, R, without footshell	1C62=R26-5-9-P/0
1C62 Trial Foot, R, Without Footshell	1C62=R26-5-P/0-OB
1C62 Trial Service Foot	1C62=R26-5-P/0-S
1C62 Triton H, R, without footshell	1C62=R27-2-2-P/0
1C62 Triton H, R, without footshell	1C62=R27-2-3-P/0
1C62 Trial Foot, R, Without Footshell	1C62=R27-2-P/0-OB
1C62 Trial Service Foot	1C62=R27-2-P/0-S
1C62 Triton H, R, without footshell	1C62=R27-3-4-P/0
1C62 Triton H, R, without footshell	1C62=R27-3-5-P/0
1C62 Trial Foot, R, Without Footshell	1C62=R27-3-P/0-OB
1C62 Trial Service Foot	1C62=R27-3-P/0-S
1C62 Triton H, R, without footshell	1C62=R27-4-6-P/0
1C62 Triton H, R, without footshell	1C62=R27-4-7-P/0
1C62 Trial Foot, R, Without Footshell	1C62=R27-4-P/0-OB
1C62 Trial Service Foot	1C62=R27-4-P/0-S
1C62 Triton H, R, without footshell	1C62=R27-5-8-P/0
1C62 Triton H, R, without footshell	1C62=R27-5-9-P/0
1C62 Trial Foot, R, Without Footshell	1C62=R27-5-P/0-OB
1C62 Trial Service Foot	1C62=R27-5-P/0-S
1C62 Triton H, R, without footshell	1C62=R28-2-2-P/0
1C62 Triton H, R, without footshell	1C62=R28-2-3-P/0
1C62 Trial Foot, R, Without Footshell	1C62=R28-2-P/0-OB
1C62 Trial Service Foot	1C62=R28-2-P/0-S
1C62 Triton H, R, without footshell	1C62=R28-3-4-P/0
1C62 Triton H, R, without footshell	1C62=R28-3-5-P/0
1C62 Trial Foot, R, Without Footshell	1C62=R28-3-P/0-OB
1C62 Trial Service Foot	1C62=R28-3-P/0-S
1C62 Triton H, R, without footshell	1C62=R28-4-6-P/0
1C62 Triton H, R, without footshell	1C62=R28-4-7-P/0
1C62 Trial Foot, R, Without Footshell	1C62=R28-4-P/0-OB
1C62 Trial Service Foot	1C62=R28-4-P/0-S
1C62 Triton H, R, without footshell	1C62=R28-5-8-P/0
1C62 Triton H, R, without footshell	1C62=R28-5-9-P/0
1C62 Trial Foot, R, Without Footshell	1C62=R28-5-P/0-OB
1C62 Trial Service Foot	1C62=R28-5-P/0-S
1C62 Triton H, R, without footshell	1C62=R29-2-2-P/0
1C62 Triton H, R, without footshell	1C62=R29-2-3-P/0
1C62 Trial Foot, R, Without Footshell	1C62=R29-2-P/0-OB
1C62 Trial Service Foot	1C62=R29-2-P/0-S

1C62 Triton H, R, without footshell	1C62=R29-3-4-P/0
1C62 Triton H, R, without footshell	1C62=R29-3-5-P/0
1C62 Trial Foot, R, Without Footshell	1C62=R29-3-P/0-OB
1C62 Trial Service Foot	1C62=R29-3-P/0-S
1C62 Triton H, R, without footshell	1C62=R29-4-6-P/0
1C62 Triton H, R, without footshell	1C62=R29-4-7-P/0
1C62 Trial Foot, R, Without Footshell	1C62=R29-4-P/0-OB
1C62 Trial Service Foot	1C62=R29-4-P/0-S
1C62 Triton H, R, without footshell	1C62=R29-5-8-P/0
1C62 Triton H, R, without footshell	1C62=R29-5-9-P/0
1C62 Trial Foot, R, Without Footshell	1C62=R29-5-P/0-OB
1C62 Trial Service Foot	1C62=R29-5-P/0-S
1C62 Triton H, R, without footshell	1C62=R30-2-2-P/0
1C62 Triton H, R, without footshell	1C62=R30-2-3-P/0
1C62 Trial Foot, R, Without Footshell	1C62=R30-2-P/0-OB
1C62 Trial Service Foot	1C62=R30-2-P/0-S
1C62 Triton H, R, without footshell	1C62=R30-3-4-P/0
1C62 Triton H, R, without footshell	1C62=R30-3-5-P/0
1C62 Trial Foot, R, Without Footshell	1C62=R30-3-P/0-OB
1C62 Trial Service Foot	1C62=R30-3-P/0-S
1C62 Triton H, R, without footshell	1C62=R30-4-6-P/0
1C62 Triton H, R, without footshell	1C62=R30-4-7-P/0
1C62 Trial Foot, R, Without Footshell	1C62=R30-4-P/0-OB
1C62 Trial Service Foot	1C62=R30-4-P/0-S
1C62 Triton H, R, without footshell	1C62=R30-5-8-P/0
1C62 Triton H, R, without footshell	1C62=R30-5-9-P/0
1C62 Trial Foot, R, Without Footshell	1C62=R30-5-P/0-OB
1C62 Trial Service Foot	1C62=R30-5-P/0-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