

## 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**

Advena Limited.  
Tower Business Centre, 2nd Flr.,  
Tower Street, Swatar, BKR 4013 Malta

SRN: MT-AR-000000234

The signatory, who represents the below-mentioned manufacturer,

**Manufacturer**

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

herewith declares under his sole responsibility that the product

**Product**

Restore

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

Basic UDI-DI:  
VS5-00: 4064409000000000VS5-00HK  
FTC-2B:4064409000000000FTC-2BFH  
FTC-3B:4064409000000000FTC-3BFL

in the following variants

**Variants**

Restore	VS5-00-01A22-RU
Restore	VS5-00-01A23-RU
Restore	VS5-00-01A23-SL
Restore	VS5-00-01A23-SR
Restore	VS5-00-01A24-RU

Restore	VS5-00-01A24-SL
Restore	VS5-00-01A24-SR
Restore	VS5-00-01A25-RU
Restore	VS5-00-01A25-SL
Restore	VS5-00-01A25-SR
Restore	VS5-00-01A26-RU
Restore	VS5-00-01A26-SL
Restore	VS5-00-01A26-SR
Restore	VS5-00-01A27-RU
Restore	VS5-00-01A27-SL
Restore	VS5-00-01A27-SR
Restore	VS5-00-01A28-RU
Restore	VS5-00-01A28-SL
Restore	VS5-00-01A28-SR
Restore	VS5-00-01A29-RU
Restore	VS5-00-01A30-RU
Restore	VS5-00-02A22-RU
Restore	VS5-00-02A23-RU
Restore	VS5-00-02A23-SL
Restore	VS5-00-02A23-SR
Restore	VS5-00-02A24-RU
Restore	VS5-00-02A24-SL
Restore	VS5-00-02A24-SR
Restore	VS5-00-02A25-RU
Restore	VS5-00-02A25-SL
Restore	VS5-00-02A25-SR
Restore	VS5-00-02A26-RU
Restore	VS5-00-02A26-SL
Restore	VS5-00-02A26-SR
Restore	VS5-00-02A27-RU
Restore	VS5-00-02A27-SL
Restore	VS5-00-02A27-SR
Restore	VS5-00-02A28-RU
Restore	VS5-00-02A28-SL
Restore	VS5-00-02A28-SR
Restore	VS5-00-02A29-RU
Restore	VS5-00-02A30-RU
Restore	VS5-00-03A22-RU
Restore	VS5-00-03A23-RU
Restore	VS5-00-03A23-SL
Restore	VS5-00-03A23-SR
Restore	VS5-00-03A24-RU
Restore	VS5-00-03A24-SL
Restore	VS5-00-03A24-SR
Restore	VS5-00-03A25-RU
Restore	VS5-00-03A25-SL
Restore	VS5-00-03A25-SR
Restore	VS5-00-03A26-RU
Restore	VS5-00-03A26-SL
Restore	VS5-00-03A26-SR
Restore	VS5-00-03A27-RU
Restore	VS5-00-03A27-SL
Restore	VS5-00-03A27-SR
Restore	VS5-00-03A28-RU
Restore	VS5-00-03A28-SL

Restore	VS5-00-03A28-SR
Restore	VS5-00-03A29-RU
Restore	VS5-00-03A30-RU
Restore	VS5-00-04A22-RU
Restore	VS5-00-04A23-RU
Restore	VS5-00-04A23-SL
Restore	VS5-00-04A23-SR
Restore	VS5-00-04A24-RU
Restore	VS5-00-04A24-SL
Restore	VS5-00-04A24-SR
Restore	VS5-00-04A25-RU
Restore	VS5-00-04A25-SL
Restore	VS5-00-04A25-SR
Restore	VS5-00-04A26-RU
Restore	VS5-00-04A26-SL
Restore	VS5-00-04A26-SR
Restore	VS5-00-04A27-RU
Restore	VS5-00-04A27-SL
Restore	VS5-00-04A27-SR
Restore	VS5-00-04A28-RU
Restore	VS5-00-04A28-SL
Restore	VS5-00-04A28-SR
Restore	VS5-00-04A29-RU
Restore	VS5-00-04A30-RU
Foot Shell, Kintrol	FTC-2B-123D4-SL
Foot Shell, Kintrol	FTC-2B-123D4-SR
Foot Shell, Kintrol	FTC-2B-123L4-SL
Foot Shell, Kintrol	FTC-2B-123L4-SR
Foot Shell, Kintrol	FTC-2B-123M4-SL
Foot Shell, Kintrol	FTC-2B-123M4-SR
Foot Shell, Kintrol	FTC-2B-124D4-SL
Foot Shell, Kintrol	FTC-2B-124D4-SR
Foot Shell, Kintrol	FTC-2B-124L4-SL
Foot Shell, Kintrol	FTC-2B-124L4-SR
Foot Shell, Kintrol	FTC-2B-124M4-SL
Foot Shell, Kintrol	FTC-2B-124M4-SR
Foot Shell, Kintrol	FTC-2B-125D4-SL
Foot Shell, Kintrol	FTC-2B-125D4-SR
Foot Shell, Kintrol	FTC-2B-125L4-SL
Foot Shell, Kintrol	FTC-2B-125L4-SR
Foot Shell, Kintrol	FTC-2B-125M4-SL
Foot Shell, Kintrol	FTC-2B-125M4-SR
Foot Shell, Kintrol	FTC-2B-126D4-SL
Foot Shell, Kintrol	FTC-2B-126D4-SR
Foot Shell, Kintrol	FTC-2B-126L4-SL
Foot Shell, Kintrol	FTC-2B-126L4-SR
Foot Shell, Kintrol	FTC-2B-126M4-SL
Foot Shell, Kintrol	FTC-2B-126M4-SR
Foot Shell, Kintrol	FTC-2B-127D4-SL
Foot Shell, Kintrol	FTC-2B-127D4-SR
Foot Shell, Kintrol	FTC-2B-127L4-SL
Foot Shell, Kintrol	FTC-2B-127L4-SR
Foot Shell, Kintrol	FTC-2B-127M4-SL
Foot Shell, Kintrol	FTC-2B-127M4-SR
Foot Shell, Kintrol	FTC-2B-128D4-SL

Foot Shell, Kintrol	FTC-2B-128D4-SR
Foot Shell, Kintrol	FTC-2B-128L4-SL
Foot Shell, Kintrol	FTC-2B-128L4-SR
Foot Shell, Kintrol	FTC-2B-128M4-SL
Foot Shell, Kintrol	FTC-2B-128M4-SR
Foot Shell Kintrol	FTC-3B-123D4-RL
Foot Shell Kintrol	FTC-3B-123D4-RR
Foot Shell Kintrol	FTC-3B-123L4-RL
Foot Shell Kintrol	FTC-3B-123L4-RR
Foot Shell Kintrol	FTC-3B-123M4-RL
Foot Shell Kintrol	FTC-3B-123M4-RR
Foot Shell Kintrol	FTC-3B-124D4-RL
Foot Shell Kintrol	FTC-3B-124D4-RR
Foot Shell Kintrol	FTC-3B-124L4-RL
Foot Shell Kintrol	FTC-3B-124L4-RR
Foot Shell Kintrol	FTC-3B-124M4-RL
Foot Shell Kintrol	FTC-3B-124M4-RR
Foot Shell Kintrol	FTC-3B-125D4-RL
Foot Shell Kintrol	FTC-3B-125D4-RR
Foot Shell Kintrol	FTC-3B-125L4-RL
Foot Shell Kintrol	FTC-3B-125L4-RR
Foot Shell Kintrol	FTC-3B-125M4-RL
Foot Shell Kintrol	FTC-3B-125M4-RR
Foot Shell Kintrol	FTC-3B-126D4-RL
Foot Shell Kintrol	FTC-3B-126D4-RR
Foot Shell Kintrol	FTC-3B-126L4-RL
Foot Shell Kintrol	FTC-3B-126L4-RR
Foot Shell Kintrol	FTC-3B-126M4-RL
Foot Shell Kintrol	FTC-3B-126M4-RR
Foot Shell Kintrol	FTC-3B-127D4-RL
Foot Shell Kintrol	FTC-3B-127D4-RR
Foot Shell Kintrol	FTC-3B-127L4-RL
Foot Shell Kintrol	FTC-3B-127L4-RR
Foot Shell Kintrol	FTC-3B-127M4-RL
Foot Shell Kintrol	FTC-3B-127M4-RR
Foot Shell Kintrol	FTC-3B-128D4-RL
Foot Shell Kintrol	FTC-3B-128D4-RR
Foot Shell Kintrol	FTC-3B-128L4-RL
Foot Shell Kintrol	FTC-3B-128L4-RR
Foot Shell Kintrol	FTC-3B-128M4-RL
Foot Shell Kintrol	FTC-3B-128M4-RR
Foot Shell Kintrol	FTC-3B-129D4-RL
Foot Shell Kintrol	FTC-3B-129D4-RR
Foot Shell Kintrol	FTC-3B-129L4-RL
Foot Shell Kintrol	FTC-3B-129L4-RR
Foot Shell Kintrol	FTC-3B-129M4-RL
Foot Shell Kintrol	FTC-3B-129M4-RR
Foot Shell Kintrol	FTC-3B-130D4-RL
Foot Shell Kintrol	FTC-3B-130D4-RR
Foot Shell Kintrol	FTC-3B-130L4-RL
Foot Shell Kintrol	FTC-3B-130L4-RR
Foot Shell Kintrol	FTC-3B-130M4-RL
Foot Shell Kintrol	FTC-3B-130M4-RR

*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**

*26 May 2021*



Dave J. Wall  
COO North America



Caleb Beck  
Director, Regulatory & Quality Compliance  
North America