

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

Kintrol

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

Basic UDI-DI:
VS4-00: 406440900000000VS4-00HC
FTC-2B: 406440900000000FTC-2BFH
FTC-3B: 406440900000000FTC-3BFL

in the following variants

Variants

Kintrol	VS4-00-01A23-RU
Kintrol	VS4-00-01A23-SL
Kintrol	VS4-00-01A23-SR
Kintrol	VS4-00-01A24-RU
Kintrol	VS4-00-01A24-SL
Kintrol	VS4-00-01A24-SR
Kintrol	VS4-00-01A25-RU

Kintrol	VS4-00-01A25-SL
Kintrol	VS4-00-01A25-SR
Kintrol	VS4-00-01A26-RU
Kintrol	VS4-00-01A26-SL
Kintrol	VS4-00-01A26-SR
Kintrol	VS4-00-01A27-RU
Kintrol	VS4-00-01A27-SL
Kintrol	VS4-00-01A27-SR
Kintrol	VS4-00-01A28-RU
Kintrol	VS4-00-01A28-SL
Kintrol	VS4-00-01A28-SR
Kintrol	VS4-00-01A29-RU
Kintrol	VS4-00-01A30-RU
Kintrol	VS4-00-02A23-RU
Kintrol	VS4-00-02A23-SL
Kintrol	VS4-00-02A23-SR
Kintrol	VS4-00-02A24-RU
Kintrol	VS4-00-02A24-SL
Kintrol	VS4-00-02A24-SR
Kintrol	VS4-00-02A25-RU
Kintrol	VS4-00-02A25-SL
Kintrol	VS4-00-02A25-SR
Kintrol	VS4-00-02A26-RU
Kintrol	VS4-00-02A26-SL
Kintrol	VS4-00-02A26-SR
Kintrol	VS4-00-02A27-RU
Kintrol	VS4-00-02A27-SL
Kintrol	VS4-00-02A27-SR
Kintrol	VS4-00-02A28-RU
Kintrol	VS4-00-02A28-SL
Kintrol	VS4-00-02A28-SR
Kintrol	VS4-00-02A29-RU
Kintrol	VS4-00-02A30-RU
Kintrol	VS4-00-03A23-RU
Kintrol	VS4-00-03A23-SL
Kintrol	VS4-00-03A23-SR
Kintrol	VS4-00-03A24-RU
Kintrol	VS4-00-03A24-SL
Kintrol	VS4-00-03A24-SR
Kintrol	VS4-00-03A25-RU
Kintrol	VS4-00-03A25-SL
Kintrol	VS4-00-03A25-SR
Kintrol	VS4-00-03A26-RU
Kintrol	VS4-00-03A26-SL
Kintrol	VS4-00-03A26-SR
Kintrol	VS4-00-03A27-RU
Kintrol	VS4-00-03A27-SL
Kintrol	VS4-00-03A27-SR
Kintrol	VS4-00-03A28-RU
Kintrol	VS4-00-03A28-SL
Kintrol	VS4-00-03A28-SR
Kintrol	VS4-00-03A29-RU
Kintrol	VS4-00-03A30-RU
Kintrol	VS4-00-04A23-RU
Kintrol	VS4-00-04A23-SL

Kintrol	VS4-00-04A23-SR
Kintrol	VS4-00-04A24-RU
Kintrol	VS4-00-04A24-SL
Kintrol	VS4-00-04A24-SR
Kintrol	VS4-00-04A25-RU
Kintrol	VS4-00-04A25-SL
Kintrol	VS4-00-04A25-SR
Kintrol	VS4-00-04A26-RU
Kintrol	VS4-00-04A26-SL
Kintrol	VS4-00-04A26-SR
Kintrol	VS4-00-04A27-RU
Kintrol	VS4-00-04A27-SL
Kintrol	VS4-00-04A27-SR
Kintrol	VS4-00-04A28-RU
Kintrol	VS4-00-04A28-SL
Kintrol	VS4-00-04A28-SR
Kintrol	VS4-00-04A29-RU
Kintrol	VS4-00-04A30-RU
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
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

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