

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

Freestyle Swim

Risk class I
according to Regulation (EU) 2017/745
Basic UDI-DI:
LP2-W2: 4064409000000000LP2-W2FH
FTC-3C: 4064409000000000FTC-3CFN

in the following variants

variants

Freestyle Swim	LP2-W2-01A22-RU
Freestyle Swim	LP2-W2-01A23-RU
Freestyle Swim	LP2-W2-01A24-RU
Freestyle Swim	LP2-W2-01A25-RU
Freestyle Swim	LP2-W2-01A26-RU
Freestyle Swim	LP2-W2-01A27-RU
Freestyle Swim	LP2-W2-01A28-RU
Freestyle Swim	LP2-W2-01A29-RU
Freestyle Swim	LP2-W2-01A30-RU
Freestyle Swim	LP2-W2-01A31-RU

Freestyle Swim	LP2-W2-02A22-RU
Freestyle Swim	LP2-W2-02A23-RU
Freestyle Swim	LP2-W2-02A24-RU
Freestyle Swim	LP2-W2-02A25-RU
Freestyle Swim	LP2-W2-02A26-RU
Freestyle Swim	LP2-W2-02A27-RU
Freestyle Swim	LP2-W2-02A28-RU
Freestyle Swim	LP2-W2-02A29-RU
Freestyle Swim	LP2-W2-02A30-RU
Freestyle Swim	LP2-W2-02A31-RU
Freestyle Swim	LP2-W2-03A22-RU
Freestyle Swim	LP2-W2-03A23-RU
Freestyle Swim	LP2-W2-03A24-RU
Freestyle Swim	LP2-W2-03A25-RU
Freestyle Swim	LP2-W2-03A26-RU
Freestyle Swim	LP2-W2-03A27-RU
Freestyle Swim	LP2-W2-03A28-RU
Freestyle Swim	LP2-W2-03A29-RU
Freestyle Swim	LP2-W2-03A30-RU
Freestyle Swim	LP2-W2-03A31-RU
Freestyle Swim	LP2-W2-04A22-RU
Freestyle Swim	LP2-W2-04A23-RU
Freestyle Swim	LP2-W2-04A24-RU
Freestyle Swim	LP2-W2-04A25-RU
Freestyle Swim	LP2-W2-04A26-RU
Freestyle Swim	LP2-W2-04A27-RU
Freestyle Swim	LP2-W2-04A28-RU
Freestyle Swim	LP2-W2-04A29-RU
Freestyle Swim	LP2-W2-04A30-RU
Freestyle Swim	LP2-W2-04A31-RU
Freestyle Swim	LP2-W2-05A22-RU
Freestyle Swim	LP2-W2-05A23-RU
Freestyle Swim	LP2-W2-05A24-RU
Freestyle Swim	LP2-W2-05A25-RU
Freestyle Swim	LP2-W2-05A26-RU
Freestyle Swim	LP2-W2-05A27-RU
Freestyle Swim	LP2-W2-05A28-RU
Freestyle Swim	LP2-W2-05A29-RU
Freestyle Swim	LP2-W2-05A30-RU
Freestyle Swim	LP2-W2-05A31-RU
Freestyle Swim	LP2-W2-06A22-RU
Freestyle Swim	LP2-W2-06A23-RU
Freestyle Swim	LP2-W2-06A24-RU
Freestyle Swim	LP2-W2-06A25-RU
Freestyle Swim	LP2-W2-06A26-RU
Freestyle Swim	LP2-W2-06A27-RU
Freestyle Swim	LP2-W2-06A28-RU
Freestyle Swim	LP2-W2-06A29-RU
Freestyle Swim	LP2-W2-06A30-RU
Freestyle Swim	LP2-W2-06A31-RU
Footshell Freestyle Swim Size 22 Dark	FTC-3C-122D4-RL
Footshell Freestyle Swim Size 22 Dark	FTC-3C-122D4-RR
Footshell Freestyle Swim Size 22 Light	FTC-3C-122L4-RL
Footshell Freestyle Swim Size 22 Light	FTC-3C-122L4-RR
Footshell Freestyle Swim Size 22 Medium	FTC-3C-122M4-RL
Footshell Freestyle Swim Size 22 Medium	FTC-3C-122M4-RR
Footshell Freestyle Swim Size 23 Dark	FTC-3C-123D4-RL

Footshell Freestyle Swim Size 23 Dark	FTC-3C-123D4-RR
Footshell Freestyle Swim Size 23 Light	FTC-3C-123L4-RL
Footshell Freestyle Swim Size 23 Light	FTC-3C-123L4-RR
Footshell Freestyle Swim Size 23 Medium	FTC-3C-123M4-RL
Footshell Freestyle Swim Size 23 Medium	FTC-3C-123M4-RR
Footshell Freestyle Swim Size 24 Dark	FTC-3C-124D4-RL
Footshell Freestyle Swim Size 24 Dark	FTC-3C-124D4-RR
Footshell Freestyle Swim Size 24 Light	FTC-3C-124L4-RL
Footshell Freestyle Swim Size 24 Light	FTC-3C-124L4-RR
Footshell Freestyle Swim Size 24 Medium	FTC-3C-124M4-RL
Footshell Freestyle Swim Size 24 Medium	FTC-3C-124M4-RR
Footshell Freestyle Swim Size 25 Dark	FTC-3C-125D4-RL
Footshell Freestyle Swim Size 25 Dark	FTC-3C-125D4-RR
Footshell Freestyle Swim Size 25 Light	FTC-3C-125L4-RL
Footshell Freestyle Swim Size 25 Light	FTC-3C-125L4-RR
Footshell Freestyle Swim Size 25 Medium	FTC-3C-125M4-RL
Footshell Freestyle Swim Size 25 Medium	FTC-3C-125M4-RR
Footshell Freestyle Swim Size 26 Dark	FTC-3C-126D4-RL
Footshell Freestyle Swim Size 26 Dark	FTC-3C-126D4-RR
Footshell Freestyle Swim Size 26 Light	FTC-3C-126L4-RL
Footshell Freestyle Swim Size 26 Light	FTC-3C-126L4-RR
Footshell Freestyle Swim Size 26 Medium	FTC-3C-126M4-RL
Footshell Freestyle Swim Size 26 Medium	FTC-3C-126M4-RR
Footshell Freestyle Swim Size 27 Dark	FTC-3C-127D4-RL
Footshell Freestyle Swim Size 27 Dark	FTC-3C-127D4-RR
Footshell Freestyle Swim Size 27 Light	FTC-3C-127L4-RL
Footshell Freestyle Swim Size 27 Light	FTC-3C-127L4-RR
Footshell Freestyle Swim Size 27 Medium	FTC-3C-127M4-RL
Footshell Freestyle Swim Size 27 Medium	FTC-3C-127M4-RR
Footshell Freestyle Swim Size 28 Dark	FTC-3C-128D4-RL
Footshell Freestyle Swim Size 28 Dark	FTC-3C-128D4-RR
Footshell Freestyle Swim Size 28 Light	FTC-3C-128L4-RL
Footshell Freestyle Swim Size 28 Light	FTC-3C-128L4-RR
Footshell Freestyle Swim Size 28 Medium	FTC-3C-128M4-RL
Footshell Freestyle Swim Size 28 Medium	FTC-3C-128M4-RR
Footshell Freestyle Swim Size 29 Dark	FTC-3C-129D4-RL
Footshell Freestyle Swim Size 29 Dark	FTC-3C-129D4-RR
Footshell Freestyle Swim Size 29 Light	FTC-3C-129L4-RL
Footshell Freestyle Swim Size 29 Light	FTC-3C-129L4-RR
Footshell Freestyle Swim Size 29 Medium	FTC-3C-129M4-RL
Footshell Freestyle Swim Size 29 Medium	FTC-3C-129M4-RR
Footshell Freestyle Swim Size 30 Dark	FTC-3C-130D4-RL
Footshell Freestyle Swim Size 30 Dark	FTC-3C-130D4-RR
Footshell Freestyle Swim Size 30 Light	FTC-3C-130L4-RL
Footshell Freestyle Swim Size 30 Light	FTC-3C-130L4-RR
Footshell Freestyle Swim Size 30 Medium	FTC-3C-130M4-RL
Footshell Freestyle Swim Size 30 Medium	FTC-3C-130M4-RR
Footshell Freestyle Swim Size 31 Dark	FTC-3C-131D4-RL
Footshell Freestyle Swim Size 31 Dark	FTC-3C-131D4-RR
Footshell Freestyle Swim Size 31 Light	FTC-3C-131L4-RL
Footshell Freestyle Swim Size 31 Light	FTC-3C-131L4-RR
Footshell Freestyle Swim Size 31 Medium	FTC-3C-131M4-RL
Footshell Freestyle Swim Size 31 Medium	FTC-3C-131M4-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

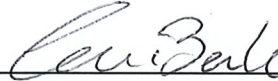
The conformity is declared based on Article 52(7), Annex II and III of the Regulation (EU) 2017/745.

Salt Lake City, Utah USA

26 May 2021



Dave J. Wall
COO North America



Caleb Beck
Director, Regulatory & Quality Compliance
North America