DECLARATION OF CONFORMITY

1) Manufacturer: NormaTec Industries, LP
Address: 480 Pleasant Street, Suite A200, Watertown, Massachusetts, United States of America, 02472
SRN: US-FM-000022838

and

2) Authorized Representative: Emergo Europe B.V.
Address: Prinsessegracht 20, 2514 AP The Hague, The Netherlands, +31 70 345 8570
SRN: NL-AR-000000116

3) Product(s):

Product Trade Name (Model Number)	Basic UDI-DI
Normatec 3 Leg Attachment – Short (63085 001-00)	00810050281829
Normatec 3 Leg Attachment – Standard (63091 001-00)	00810050281720
Normatec 3 Leg Attachment – Tall (63095 001-00)	00810050282116
Normatec 3 Leg Attachment – Short Power (67070 001-00)	00810050281881
Normatec 3 Leg Attachment – Standard Power (67080 001-00)	00810050281911
Normatec 3 Leg Attachment – Tall Power (67090 001-00)	00810050281942
Normatec 3 Arm Attachment – Left – Single (63075 001-21)	00810050281805
Normatec 3 Arm Attachment – Right -Single (63075 001-22)	00810050281812
Normatec 3 Hip Attachment – Single (60061 001-00)	00810050282406

4) The product(s) described above is/ are in conformity with:

Title	Document No.
Medical Device Regulation	(EU) 2017/745
RoHS Directive	2011/65/EU

These products are fully compliant and do not contain the restricted substances above level noted in RoHS Directive 2011/65/EU.

5) Intended Purpose: Inflatable attachment for use with Normatec 3 Control Device.

6) Additional Information:

Technical Documentation compiled according to:	Annex II and III of Regulation MDR (EU) 2017/745
Classification:	Class I in accordance with Annex VIII, rule 1 of Regulation MDR (EU) 2017/745

This declaration of conformity is issued under the sole responsibility of the manufacturer, NormaTec Industries, LP.

Steve Henderson
Director of Quality & Regulatory Systems

2023 January 3 / Watertown MA USA
Date / Location