



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 Hose (63080 001-00)	00810050281713

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

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

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

5) Intended Purpose: Air tubing for connecting Normatec 3 Control Device to Normatec 3 Attachments.

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