

EUROPEAN DECLARATION OF CONFORMITY

This European Declaration of Conformity is issued under the sole responsibility of the manufacturer.

RESPINOR AS declares, under its sole responsibility, that the product(s) covered in the table below are in conformance with the following Regulation(s) and Directive(s):

Medical Devices Regulations (EU) 2017/745 and Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment, including its subsequent amendments and carried out according to the Quality Management System EN ISO 13485:2016¹.

Manufacturer Name	RESPINOR AS
Manufacturer Address	Gaustadalléen 21, 0349 Oslo, Norway
Manufacturer SRN	NO-MF-000012955
Product Names	DXT 4.0 Control Unit DXT 4.0 Sensor Kit (5 pcs)
Article Numbers	DXT 4.0 Control Unit: 970-0003 DXT 4.0 Sensor Kit (5 pcs): 990-0003
Basic UDI-DI	DXT 4.0 Control Unit: 709005853DXTADL DXT 4.0 Sensor Kit: 709005853DXTSADE
Intended purpose	RESPINOR DXT® provides real-time continuous monitoring of diaphragm movement.
Classification	Class IIa, Rule 10
Notified Body	TÜV SÜD Product Service GmbH Ridlerstraße 65 80339 München – Germany
Notified Body number	0123
EU Certificate Number	G15 115644 0002 Rev. 00 valid from 2025-07-31 to 2030-07-30
Conformity Assessment Route	Annex IX, Chapters I of Regulation (EU) 2017/745 (MDR).
Name	Geir Torheim
Title	Director RA & QA (PRRC according to MDR article 15)
Signature and date	<i>Geir Torheim</i> <small>Geir Torheim (Aug 12, 2025 09:37:10 GMT+2)</small>

¹ This declaration of Conformity is valid until withdrawn or reissued due to significant product change, new product code or new/changed/ regulatory/legal requirements.

MDR-0009 R3 RESPINOR DXT 4.0 Declaration of Conformity

Final Audit Report

2025-08-12

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