EC CERTIFICATION

QUALITY MANAGEMENT SYSTEM CERTIFICATE

Regulation (EU) 2017/745 for Medical Devices, Annex IX Chapters I & III

We hereby declare that a conformity assessment based on a quality management system and technical documentation has been carried out following the requirements of Regulation (EU) 2017/745 for Medical Devices.

We certify that the documentation conforms to the relevant provisions of the aforementioned regulation, and the result entitles the organization to use the CE 2862 marking on the products listed below.

Ortivus MobiMed AB

Svärdvägen 19, SE-182 33 Danderyd, Sweden

Manufacturer SRN: SE-MF-000003568

Scope:

- Patient monitoring devices

Certificate Number:
28620161156

Revision:
00

Initial Certification Date:
28 November 2023

Certificate Decision Date:
28 November 2023

Certificate Issue Date:
28 November 2023

Certificate Expiry Date:
27 November 2028

Brian Mather
Certification Authority, MDR
Intertek Medical Notified Body AB,
Torshamnsgatan 43,
Box 1103, SE-164 22 Kista, Sweden

Intertek Medical Notified Body AB is a Notified Body in accordance with the requirements set out in EU Regulation 2017/745 on medical devices, with the identification number 2862.

PRODUCT LIST FOR CERTIFICATE

See attached product list

EXAMINATION AND TESTS PERFORMED

Technical Assessment Report Reference	**TD00294-01 Ortivus MobiMed AB MobiMed Monitor**
Audit Report Reference	**Stage 1 audit ACTY-2022-589001**
	Stage 2 audit ACTY-2022-589231

CONDITIONS FOR OR LIMITATIONS TO VALIDITY OF CERTIFICATE

None

CERTIFICATE HISTORY

PRECEDING CERTIFICATE NUMBER	DATE OF ISSUE	IDENTIFICATION OF CHANGES

Certificate Number:
28620161156

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