

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

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

Kret

Brian Mather Certification Authority, MDR Intertek Medical Notified Body AB, Torshamnsgatan 43, Box 1103, SE-<u>164</u> 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.





In the issuance of this certificate, Intertek assumes no liability to any party other than to the Client, and then only in accordance with the agreed upon Certification Agreement. This certificate's validity is subject to the organization maintaining their system in accordance with Intertek's requirements for systems certification. Validity may be confirmed via email at certificate.validation@intertek.com or by scanning the code to the right with a smartphone.

The certificate remains the property of Intertek, to whom it must be returned upon request.



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

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CERTIFICATE HISTORY

PRECEDING CERTIFICATE NUMBER	DATE OF ISSUE	IDENTIFICATION OF CHANGES