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.

Hermes Medical Solutions AB

Strandbergsgatan 16, SE-112 51 Stockholm, Sweden

Manufacturer SRN: SE-MF-000023032

Scope:

- Software

Certificate Number:
28620167501

Revision:
01

Initial Certification Date:
14 February 2024

Certificate Decision Date:
8 March 2024

Certificate Issue Date:
8 March 2024

Certificate Expiry Date:
3 October 2028

Brian Mather
Certification Authority, MDR
Intertek Medical Notified Body AB,
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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	**TD00311-01 HERMES Medical Solutions AB OLINDA//EXM**
	TD00311-02 HERMES Medical Solutions AB Hybrid Viewer
Audit Report Reference	**Stage 1 audit ACTY-2023-623060**
	Stage 2 audit ACTY-2023-623061

CONDITIONS FOR OR LIMITATIONS TO VALIDITY OF CERTIFICATE

None

CERTIFICATE HISTORY

PRECEDING CERTIFICATE NUMBER	DATE OF ISSUE	IDENTIFICATION OF CHANGES
28620167501	14 Feb 2024	Initial certificate

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PRODUCT LIST FOR CERTIFICATE

Issued to: Hermes Medical Solutions AB

Certificate number: 28620167501-01

Certificate valid from: 2024-03-08

Product List Issue Date:
08 March 2024

Product	Classification and EMDN	Intended use[1]	Date Added
Medical Device Software			
Basic UDI-DI: 085987300600066			
UDI-DI=00859873006196 - Hybrid Recon	Class IIa Z11029092	Hybrid Recon is a software application for nuclear medicine. Based on user input, Hybrid Recon reconstructs the nuclear medicine imaging acquisition study. The result can be stored for future analysis. The software application can be configured based on user needs. Hybrid Recon can also optionally be used to assess the quality of the acquired studies and perform motion correction when required, as well as produce quantitative SUV (Standardized Uptake Value) reconstructed studies.	2024-02-14
Basic UDI-DI: 085987300600168			
UDI-DI=00859873006189 - Hybrid Viewer	Class IIa Z11029092	Hybrid Viewer is a software application for nuclear medicine and radiology. Based on user input, Hybrid Viewer process, display and analyze nuclear medicine and radiology imaging data and present the result to the user. The result can be stored for future analysis. Hybrid Viewer is equipped with dedicated workflows which have predefined settings and layouts optimized for specific nuclear medicine investigations. The software application can be configured based on user needs. The investigation of physiological or pathological states using measurement and analysis functionality provided by Hybrid Viewer is not intended to replace visual assessment. The information obtained from viewing and/or performing quantitative analysis on the images is used, in conjunction with other patient related data, to inform clinical management.	2024-02-14
Basic UDI-DI: 08598730060026A			
UDI-DI=00859873006202 - Voxel Dosimetry	Class IIb Z11029092	Voxel Dosimetry is a software application for nuclear medicine. Based on user input of nuclear medicine image data, Voxel Dosimetry calculates a volumetric map of the distribution of absorbed radiation dose (a dose map) on the voxel level and presents the results to the user. The result can be stored for future analysis. Voxel Dosimetry can calculate the predicted dose map of a different radionuclide or different injected activity based on an image of the first measured radionuclide. The dose distribution estimated by Voxel Dosimetry may guide the decision making for future patient radionuclide therapy treatments or inform radiation protection measures for diagnostic radiopharmaceuticals. The software application can be configured based on user needs.	2024-02-14
Basic UDI-DI: 08598730060036C			

[1]The intended use is only included for class IIb devices and devices covered by an EU technical documentation certificate.

Product	Classification and EMDN	Intended use[1]	Date Added
UDI-DI=00859873006219 - OLINDA//EXM	Class IIb Z11029092	OLINDA/EXM® is a software application for nuclear medicine. Based on user input of time integrated activity in separate organs, OLINDA/EXM® calculates the organ dose and the whole-body dose and presents the result to the user. The result can be stored for future analysis. The dose estimates provided by OLINDA/EXM® may guide the decision making for future patient radionuclide therapy treatments or inform radiation protection measures for diagnostic radiopharmaceuticals.	2024-02-14
Basic UDI-DI: 08598730060046E			
UDI-DI=00859873006172 - Affinity	Class IIa Z11029092	Affinity is a software application for nuclear medicine and radiology. Based on user input, Affinity processes, displays and analyzes nuclear medicine and radiology imaging data and presents the result to the user. The result can be stored for future analysis. The software application can be configured based on user needs. The investigation of physiological or pathological states using measurement and analysis functionality provided by Affinity is not intended to replace visual assessment. The information obtained from viewing and/or performing quantitative analysis on the images is used, in conjunction with other patient related data, to inform clinical management.	2024-02-14

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[1]The intended use is only included for class IIb devices and devices covered by an EU technical documentation certificate.

Certificate number: 28620167501-01
Product list issue date: 08 March 2024