# EC CERTIFICATION

## QUALITY MANAGEMENT SYSTEM CERTIFICATE

### EU Regulation 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 restricted to the aspects relating to the conformity of the devices with metrological requirements - 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.

**Certificate Number:**
28620160804

**Revision:**
00

**Initial Certification Date:**
23 November 2023

**Certificate Decision Date:**
23 November 2023

**Certificate Issue Date:**
23 November 2023

**Certificate Expiry Date:**
18 December 2027

## ScandiDos AB

Dag Hammarskjölds väg 52A, third floor SE-752 37, Uppsala, Sweden

Manufacturer SRN: SE-MF-000035494

**Scope:**

Metrology aspects of devices as detailed in attached product list.

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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.