By Royal Charter

EU Technical Documentation Assessment Certificate

Regulation (EU) 2017/746, Annex IX Chapter II

IVDR 740032 R000

Manufacturer: Radiometer Medical ApS

Address:
Åkandevej 21
Brønshøj
2700
Denmark

Single Registration Number: DK-MF-000016271

Scope: See attached **Device Schedule**

On the basis of our assessment of the technical documentation in accordance with Regulation (EU) 2017/746, Annex IX Chapter II, the technical documentation meets the requirements of the Regulation. For the placing on the market of these devices an additional Annex IX Chapter I and III certificate is required.

For and on behalf of BSI, a Notified Body for the above Regulation (Notified Body Number 2797):

Graeme Tunbridge, Senior Vice President Medical Devices

First Issue Date: **2023-01-23**

Current Issue Date: **2023-01-23**

Starting Validity Date: **2023-01-23**

Expiry Date: **2028-01-22**

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Device Schedule:

Intended Purpose as per the Instructions for Use:

For *in vitro* diagnostic use.
The Myo Test is an *in vitro* diagnostic assay for the quantitative determination of myoglobin (Myo) in EDTA or lithium heparin whole blood or plasma specimens on the AQT90 FLEX analyzer in point of care / near-patient testing and laboratory settings. It is intended for use as an aid in the rapid diagnosis of myocardial infarction.
The Myo CAL Cartridges are *in vitro* diagnostic reagents intended for the calibration adjustment of the Myo Test on the AQT90 FLEX analyzer by establishing points of reference to estimate myoglobin (Myo) values.

Device Name	**Model**	**Type** (Codes as per (EU) 2017/2185)	**Risk Classification**	**Basic UDI-DI**
Myo Test Kit	942-909	IVR 0605	Class C near-patient test	57006900017MS
Myo CAL Cartridge	944-214	IVR 0605	Class C near-patient test	57006900018MU

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Certificate History

(References to applicable Common Specifications, Harmonized Standards complied with, and the relevant test and audit reports that support any of the below certificate changes may be requested from Certificate.Verification@bsigroup.com)

Date	Reference Number	Action
Current	3329958	Issued

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Validity of this certificate is conditional on the Manufacturer's quality system being maintained to the requirements of the Regulation as demonstrated through the required surveillance activities of the Notified Body.
This certificate was issued electronically and is bound by the conditions of the contract.

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