

EU Technical Documentation Assessment Certificate

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

IVDR 740026 R000

Manufacturer: Radiometer Medical ApS

Address:

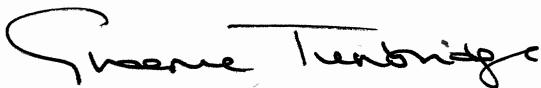
Åkandevvej 21
Brønshøj
2700
Denmark

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 Issued: **2022-07-18**

Date: **2022-07-18**

Expiry Date: **2027-07-17**

...making excellence a habit.™

Page 1 of 3

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.

NB Contact: BSI Group The Netherlands B.V., Say Building, John M. Keynesplein 9, 1066 EP, Amsterdam, Netherlands. Tel: + 31 (0) 20 346 07 80
Corporate Contact: BSI Group Assurance Limited, registered in England under number 05435540 at 389 Chiswick High Road, London, W4 4AL, UK.
A Member of the BSI Group of Companies.

EU Technical Documentation Assessment Certificate

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

IVDR 740026 R000

Device Schedule:

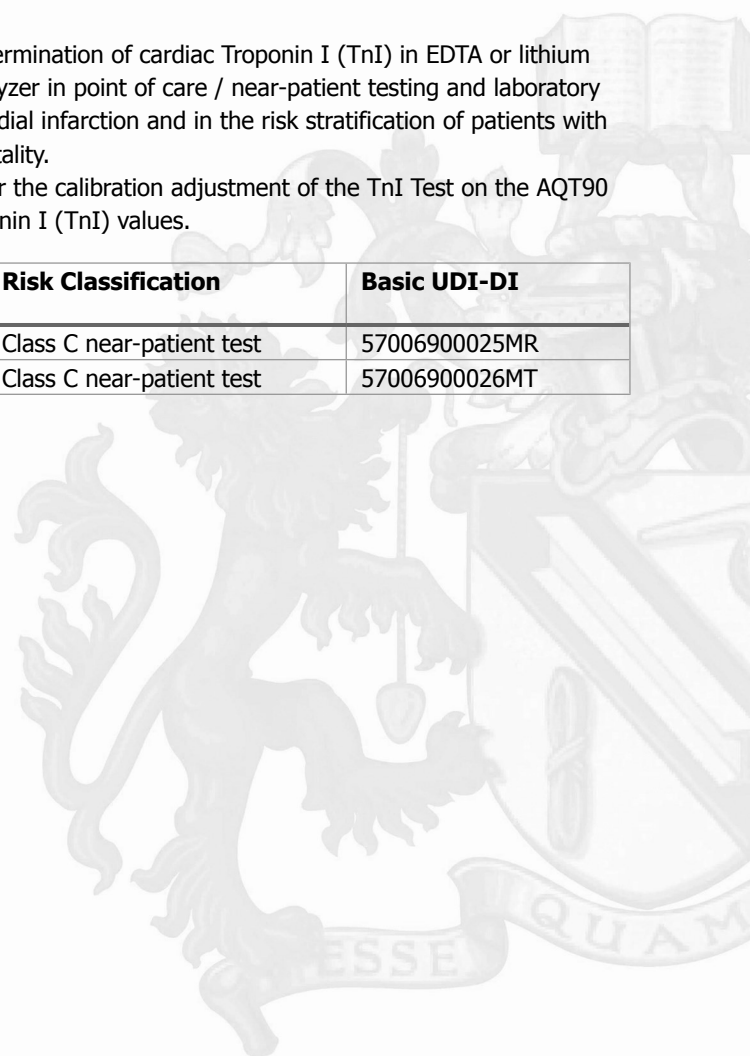
Intended Purpose as per the Instructions for Use:

For *in vitro* diagnostic use.

The TnI Test is an *in vitro* diagnostic assay for the quantitative determination of cardiac Troponin I (TnI) 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 indicated for use as an aid in the diagnosis of myocardial infarction and in the risk stratification of patients with acute coronary syndromes with respect to their relative risk of mortality.

The TnI CAL Cartridges are *in vitro* diagnostic reagents intended for the calibration adjustment of the TnI Test on the AQT90 FLEX analyzer by establishing points of reference to estimate Troponin I (TnI) values.

Device Name	Model	Type (Codes as per (EU) 2017/2185)	Risk Classification	Basic UDI-DI
TnI Test Kit	942-903	IVR 0605	Class C near-patient test	57006900025MR
TnI CAL Cartridge	944-212	IVR 0605	Class C near-patient test	57006900026MT



First Issued: **2022-07-18**

Date: **2022-07-18**

Expiry Date: **2027-07-17**

...making excellence a habit.™

Page 2 of 3

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.

NB Contact: BSI Group The Netherlands B.V., Say Building, John M. Keynesplein 9, 1066 EP, Amsterdam, Netherlands. Tel: + 31 (0) 20 346 07 80
Corporate Contact: BSI Group Assurance Limited, registered in England under number 05435540 at 389 Chiswick High Road, London, W4 4AL, UK.
A Member of the BSI Group of Companies.

EU Technical Documentation Assessment Certificate

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

IVDR 740026 R000

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	3329949	Issued



First Issued: **2022-07-18**

Date: **2022-07-18**

Expiry Date: **2027-07-17**

...making excellence a habit.™

Page 3 of 3

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.

NB Contact: BSI Group The Netherlands B.V., Say Building, John M. Keynesplein 9, 1066 EP, Amsterdam, Netherlands. Tel: + 31 (0) 20 346 07 80
Corporate Contact: BSI Group Assurance Limited, registered in England under number 05435540 at 389 Chiswick High Road, London, W4 4AL, UK.
A Member of the BSI Group of Companies.