

EU Technical Documentation Assessment Certificate

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

IVDR 740016 R000

Manufacturer: Radiometer Medical ApS

Address:

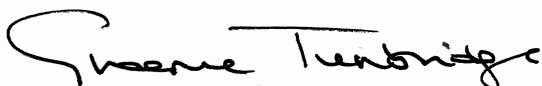
Åkandevej 21
Brønshøj
2700
Denmark

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: **2023-01-30**

Current Issue Date: **2023-01-30**

Starting Validity Date: **2023-01-30**

Expiry Date: **2028-01-29**

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Device Schedule:

For *in vitro* diagnostic use.

The β hCG Test is an *in vitro* diagnostic assay for the quantitative determination of human chorionic gonadotropin (hCG) plus beta subunit human chorionic gonadotropin (β hCG) 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 early detection of pregnancy. It is not indicated as a surrogate marker in the diagnosis or monitoring of cancer patients.

The β hCG CAL cartridges are *in vitro* diagnostic reagents intended for the calibration adjustment of the β hCG Test on the AQT90 FLEX analyzer by establishing points of reference to estimate total β hCG values.

Device Name	Model	Type (Codes as per (EU) 2017/2185)	Risk Classification	Basic UDI-DI
β hCG Test Kit	942-918	IVR 0607	Class B near-patient test	57006900015MN
β hCG CAL Cartridge	944-222	IVR 0607	Class B near-patient test	57006900016MQ

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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.

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.
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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	3329941	Issued



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