

# EU Quality Management System Certificate

Regulation (EU) 2017/746, Annex IX Chapter I and III

## IVDR 742056 R000

**Manufacturer:** Waters Corporation

**Address:**

34 Maple Street  
Milford  
Massachusetts  
01757  
USA

**Single Registration Number:** US-MF-000025801

**EU Authorised Representative:** Emergo Europe B.V.

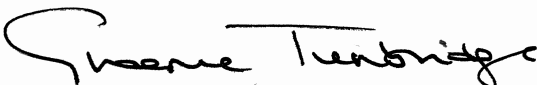
**Address:**

Westervoortsedijk 60  
6827 AT Arnhem  
The Netherlands

**Scope:** See attached **Device Schedule**

On the basis of our examination of the quality system in accordance with Regulation (EU) 2017/746, Annex IX Chapter I and III, the quality system meets the requirements of the Regulation. For the placing on the market of Class D devices, and self-test, near-patient test and companion diagnostic devices an Annex IX Chapter II 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: **2022-01-20**

Current Issue Date: **2023-03-28**

Starting Validity Date: **2023-03-28**

Expiry Date: **2027-01-19**

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### Device Schedule: Class D, C and B devices

Class B Devices	Intended purpose
IVR 0608 - Devices intended to be used for screening, determination or monitoring of physiological markers	In vitro diagnostic devices intended for the quantitative determination of physiological markers in serum and plasma by Mass Spectrometry.



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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
2022-01-20	3348415	Issued
Current	3867221	Amended - Change of Address of Authorised EU Rep



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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.  
A Member of the BSI Group of Companies.