

EU Quality Management System Certificate

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

IVDR 724873 R000

Manufacturer: IBL International GmbH

Address:

Flughafenstrasse 52A
22335 Hamburg
Germany

Single Registration Number: Not Available

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-patent 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):



Gary E Slack, Senior Vice President Medical Devices

First Issued: **2021-01-27**

Date: **2021-01-27**

Expiry Date: **2026-01-26**

...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.

EU Quality Management System Certificate

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

IVDR 724873 R000

Device Schedule: Class B devices

Class B

Subcategory group - IVR0608

Intended purpose

Measurement of DHEA physiological marker as an aid in the diagnosis and treatment of suspected dysfunction of the adrenal gland.



First Issued: **2021-01-27**

Date: **2021-01-27**

Expiry Date: **2026-01-26**

...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.

EU Quality Management System Certificate

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

IVDR 724873 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	3151011	First Issue



First Issued: **2021-01-27**

Date: **2021-01-27**

Expiry Date: **2026-01-26**

...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.