By Royal Charter

EU Quality Management System Certificate

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

IVDR 738335 R000

Manufacturer: Immunotech s.r.o.

Address:
Radiova 1122/1
Prague 10
102 00
Czech Republic

Single Registration Number: CZ-MF-000001761

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: **2022-01-24**

Current Issue Date: **2022-10-19**

Starting Validity Date: **2022-10-19**

Expiry Date: **2027-01-23**

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Device Schedule:

Class B devices	Intended purpose
IVR 0602 Devices intended to be used for screening, determination or monitoring of physiological markers for a specific disease.	Immunoassay/radioimmunoassay devices intended to be used for screening, determination or monitoring of physiological markers for a specific disease.
IVR 0603 Devices intended to be used for screening, confirmation / determination, or monitoring of allergies and intolerances.	Immunoassay/radioimmunoassay devices intended to be used for screening, confirmation / determination, or monitoring of allergies and intolerances.
IVR 0607 Devices intended to be used for detection of fertility and fertility related disorders.	Immunoassay/radioimmunoassay devices intended to be used for detection of fertility and fertility related disorders.

Class C devices	Intended purpose
W0102 – IMMUNOCHEMISTRY (IMMUNOLOGY) IVP 3007 – in vitro diagnostic devices which require knowledge regarding immunoassays	Immunoassay/radioimmunoassay devices intended to be used for the diagnosis, prognosis or monitoring of cancer
W0102 – IMMUNOCHEMISTRY (IMMUNOLOGY) IVP 3007 – in vitro diagnostic devices which require knowledge regarding immunoassays	Radioimmunoassay devices intended to be used for the diagnosis of life threatening diseases.
W0102 – IMMUNOCHEMISTRY (IMMUNOLOGY) IVP 3007 – in vitro diagnostic devices which require knowledge regarding immunoassays	Immunoassay/radioimmunoassay devices intended to be used for the diagnosis of congenital diseases
W0102 – IMMUNOCHEMISTRY (IMMUNOLOGY) IVP 3007 – in vitro diagnostic devices which require knowledge regarding immunoassays	Radioimmunoassay devices intended to be used for the monitoring of medicinal substances

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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
2022-01-24	3314099	Issued
Current	3757382	Addition of generic device groups: Class C W0102, IVP 3007 Diagnosis, prognosis or monitoring of cancer W0102 IVP 3007 diagnosis of life threatening diseases W0102 IVP 3007 diagnosis of congenital diseases W0102 IVP 3007 monitoring of medicinal substances

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