

# EU Quality Management System Certificate

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

## IVDR 795001 R000

**Manufacturer:** Laboratory Imaging s.r.o.

**Address:**

Za drahou 171/17

Prague

102 00

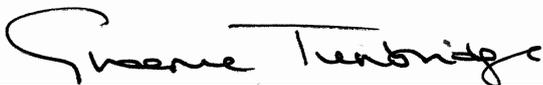
Czech Republic

**Single Registration Number:** CZ-MF-000025008

**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 Global Regulatory & Quality

First Issue Date: **2025-05-09**

Current Issue Date: **2025-05-09**

Starting Validity Date: **2025-05-09**

Expiry Date: **2030-05-08**

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

Class C devices	Intended purpose
W0202 – Hematology / Histology / Cytology Instruments	In vitro diagnostic medical device software for chromosome analysis (digital karyotyping and FISH) by means of digital image manipulation for diagnosis of chromosomal disorders or risk factors.
IVP3004 – In vitro diagnostic devices which require knowledge regarding chromosomal analysis	



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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	30004125	Issued



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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.

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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.