EU Quality Management System Certificate

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

IVDR 751166 R000

Manufacturer: MetaSystems Probes GmbH

Address:
1. Industriestrasse 7
68804 Altlussheim
Germany

Single Registration Number: DE-MF-000006315

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: **2023-11-20**

Current Issue Date: **2024-10-25**

Starting Validity Date: **2024-10-25**

Expiry Date: **2028-11-19**

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Device Schedule: Class D, C and B devices

Class C devices	Intended purpose
W010601 – Inborn Gene or Chromosome Alterations IVP 3004 – In vitro diagnostic devices which require knowledge regarding chromosomal analysis	Fluorescence in situ hybridization (FISH) devices designed to identify or rule out a specific chromosomal condition, including chromosomal abnormalities in foetus' before birth.
W010602 – Acquired Gene or Chromosome Alterations IVP 3004 – In vitro diagnostic devices which require knowledge regarding chromosomal analysis	Fluorescence in situ hybridization (FISH) devices designed to aid in diagnosis and to assist in disease monitoring of cancer by detection of acquired chromosomal alterations.

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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
2023-11-20	3448620	Issued
Current	30263962	Supplemented – Addition of group W010601 + IVP 3004 W0106 updated to W010602 for the already certified group.

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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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