

EU Quality Management System Certificate

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

IVDR 751166 R000

Manufacturer: MetaSystems Probes GmbH

Address:

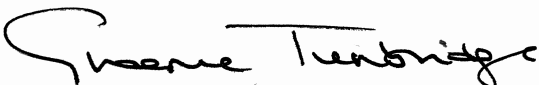
1. Industriestrasse 7
68804 Altussheim
Germany

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 Medical Devices

First Issue Date: **2023-11-20**

Current Issue Date: **2023-11-20**

Starting Validity Date: **2023-11-20**

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

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Device Schedule: Class D, C and B devices

Class C devices	Intended purpose
W0106 – Genetic testing	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.
IVP 3004- 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	3448620	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.