By Royal Charter

EC Certificate - Full Quality Assurance

Directive 98/79/EC on In Vitro Diagnostic Medical Devices (IVDD), Annex IV, excluding Sections 4 and 6

No. **CE 635223**

Issued To: **MetaSystems Probes GmbH**
1. Industriestrasse 7
68804 Altlussheim
Germany

In respect of:

Design and manufacture of FISH DNA probes for the evaluation of the risk of Trisomy 21.

Entwicklung und Herstellung von FISH DNA Sonden zur Ermittlung des Risikos von Trisomie 21.

Développement et production des sondes ADN pour l'évaluation du risque de trisomie 21.

on the basis of our examination under the requirements of Council Directive 98/79/EC, Annex IV, the quality system was found to meet the requirements of 98/79/EC Annex IV.

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 2797):

Gary E Slack, Senior Vice President Medical Devices

First Issued: **2016-07-01** Date: **2021-06-01** Expiry Date: **2024-05-26**

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Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive. For the placing on the market of List A devices covered by this certificate, an EC Design-Examination Certificate according to 98/79/EC Annex IV Section 4 is required and a letter releasing each batch according to Annex IV Section 6.
This certificate was issued electronically and is bound by the conditions of the contract.

Digitally signed by Plămădeală Inga
Date: 2022.11.23 08:34:17 EET
Reason: MoldSign Signature
Location: Moldova

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