SERANA®

Statement: Declaration of Conformity
Cytogenetics Products

To whom it may concern

We, Serana Europe GmbH, being:

- ISO 13485:2016 Certified as the manufacturer and distributor of cell culture and In-vitro Diagnostics products (certificate attached), and

- the manufacturer of the following products

Product Code	Product Group	Product Description	Options	Volume	Storage
AMG-001-100ML	Cytogenetics	Amniogrow™, Complete Medium for Cultivation of Amnion and Chorionic Villi Cells	Sterile Filtered	100 mL	< - 15°C
LMG-001-100ML	Cytogenetics	Lymphogrow™, Complete Karyotyping Medium for Peripheral Blood Lymphocytes	Sterile Filtered	100 mL	< - 15°C
CDS-001-10ML	Cytogenetics	Phytohemagglutinin (PHA-M)	Sterile Filtered	10 mL	< - 15°C
CDS-002-10ML	Cytogenetics	Colcemid Solution (10 µg/ml) in DPBS	Sterile Filtered	10 mL	2 to 8°C

declare that the above products are manufactured following the Regulation (EU) 2017/746 for the In Vitro Diagnostic Medical devices Class A sterile. The application and certification are in progress and our customers will be notified upon receiving the IVDR/CE certificate. Please see more details in the current version of the products' Technical Datasheets in the attachment. Please do not hesitate to contact us if you may have further questions.

Sincerely yours

SERANA®
Science for Life
Serana Europe GmbH
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Digitally signed by Rusu Ghenadie
Date: 2024.02.06 18:27:37 EET
Reason: MoldSign Signature
Location: Moldova

Dr. Iman Kamranfar
Head of Quality
Serana Europe GmbH
Date: 24/01/2024