3EC International a.s., Hraničná 18, 821 05 Bratislava, Slovak Republic
Notified body No. 2265

# EU QUALITY MANAGEMENT SYSTEM CERTIFICATE
# No. 2024-MDR/QS-026

## Synga, s.r.o.

**Head Office: Voděradská 2552/16, 251 01 Říčany, Czech Republic**
**Manufacturing site: Podnikatelská 565, Běchovice, 190 11 Praha 9, Czech Republic**
**SRN No.: CZ-MF-000032524**

This EU Quality Management System Certificate issued in accordance with the Regulation (EU) 2017/745 of the European Parliament and of the Council on medical devices as amended confirms, that quality management system of medical device:

**Micropipettes SG System for human embryo/oocyte manipulation in vitro**
**Variants: Denudation SG Pipette, Manipulation SG Pipette, Blastocyst SG Pipette, Denudation SG Flex Pipette, Manipulation SG Flex Pipette, Blastocyst SG Flex Pipette, SG Holding Pipette, SG ICSI Pipette, SG Biopsy Pipettes, SG Hatching Pipette**
(for detailed list refer to Annex I)
**Intended purpose: Annex II**
**MD class Is**
(detailed list is stated in the annex(es) if applicable)

**meets the requirements on quality management system according to the Chapter I and III of Annex IX of the Regulation (EU) 2017/745 of the European Parliament and of the Council on medical devices as amended.**

Conditions for or limitations to the validity of the certificate: **N/A**

For class Is devices, the audit by the NB2265 of the quality management system was limited to the aspects relating to establishing, securing and maintaining sterile conditions.

Validity of the certificate is conditional upon positive results of regular surveillance audits.

Notified body No. 2265 has performed assessment of the quality management system of the abovementioned medical device and found that it meets the requirements stated above. The outcome of the assessment of the quality management system of the abovementioned medical device is stated in the MD Audit Report No. SK-0508-24 from April 19, 2024. Information on all examinations and tests performed is stated in the abovementioned report and is available on request.

This **EU Quality Management System Certificate** applies only to the quality management system of the abovementioned medical device. The certificate validity is conditional upon fulfilment of relevant legal requirements by the manufacturer.

Valid from: **April 26, 2024**
Valid until: **April 26, 2029**
First issue: **April 26, 2024**
Revision: **00**
History: **Annex III**

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**3EC International a.s.**
**Katarína Tomin Srdošová, PhD.**
Director of NB2265

In Bratislava, Slovakia, April 26, 2024