



3EC International a.s., Hraničná 18, 821 05 Bratislava, Slovakia  
Notified Body No. 2265

## EC CERTIFICATE

No. 2020-MDD/QS-056

issued in compliance with the Council Directive 93/42/EEC as amended,  
which is implemented by the Slovak Government Decree No. 582/2008 Coll. as amended by 215/2013  
Coll. certifies that the medical device of Class I sterile,

**Micropipettes SG System for human embryo/oocyte manipulation in vitro**

**Model: 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 Pipette**

manufactured by company

**Synga, s.r.o.**  
Voděradská 2552/16, 251 01, Říčany, Czech Republic


is manufactured under conditions fulfilling the quality system requirements of Annex V of the  
Directive 93/42/EEC as amended.

The Notified Body No. 2265 has performed an audit of the above device quality system – restricted to  
aspects of manufacture concerned with securing and maintaining sterile conditions. The quality system  
has been assessed, approved and is subject to continuous surveillance according to Annex V, Section 4,  
of the Directive 93/42/EEC as amended. The detailed description of the system, requirements and  
measures applied by the manufacturer are presented in the Audit Report No. ICT\_34 and the Final  
protocol No. 310474/2020.

*This certificate is issued under the following conditions:*

It applies only to the quality system maintained in the manufacture of the above referenced model of  
medical device and it does not substitute the design or type-examination procedures, if requested. The  
certificate remains valid until the manufacturing conditions or the quality system are changed but until  
May 26<sup>th</sup>, 2024 at the latest. The certificate validity is conditional upon positive results of regular  
surveillance audits and fulfillment of relevant legal and other requirements by manufacturer.



  
Dr. Katarina Tomin Srdošová  
Responsible to act on behalf of NB 2265

At Bratislava, on May 8<sup>th</sup>, 2020

This EC Certificate supersedes the EC Certificate No. 2016-MDD/QS-015 issued on June 30<sup>th</sup>, 2016