SYNGA
TOUCHING LIFE GENTLY

EC DECLARATION OF CONFORMITY

issued in compliance with the Council Directive 93/42/EEC as amended 2007/47/EC concerning medical devices

Manufacturer:
Synga, s.r.o., Voděradská 2552/16, Říčany u Prahy, Czech Republic
Hereby declares that product

Micropipettes SG System for human embryo/oocyte manipulation in vitro

models Denudation SG Pipette, Manipulation SG Pipette and Blastocyst SG Pipette, Denudation SG Flex Pipette, Manipulation SG Flex Pipette and Blastocyst SG Flex Pipette, SG Holding Pipette, SG ICSI Pipette, SG Biopsy Pipette

meets the essential requirements of Directive 93/42 / EEC as amended and is, in normal use, safe for its purpose according to the instructions for use and the manufacturer has taken measures to ensure that all medical devices placed on the market comply with their technical documentation and essential requirements.

Applied standards:
Council Directive 93/42 / EEC as amended
Government Regulation 54/2015 Coll. as amended
Act 102/2001 Coll. as amended
ČSN EN ISO 13485:2016
ČSN EN ISO 14971:2013
ČSN EN 556-1:2002
ČSN EN ISO 15223-1:2016

Council Directive 93/42 / EEC, as amended, Annex V, classification rule 1 was used to assess the essential characteristics of the product in the prescribed manner.
The conformity was assessed with the participation of the Notified Body No. 2265, 3EC International a.s., Hraničná 18, 821 05 Bratislava, Slovakia, certificate number No. 2020-MDD / QS-056 dated 8.5. 2020.

Říčany 10.6. 2020

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Touching life gently
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