SYNGA
TOUCHING LIFE GENTLY

CE 2265

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., Želivská 1955, 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
classification Class Is (according to Annex IX, Rule 1 of MDD 93/42/EEC)

meet essential requirements set out in the Annex I of the Directive 93/42/EEC. The products are safe under prescribed and reasonably foreseeable conditions of storage and use.

Applied standards:
Directive 93/42/EHS
Directive 2007/47/EC
ČSN EN ISO 14971
ČSN ISO 3585:1999 – čl. 4.1-4, čl. 5.1-6
ISO 7086-2:2000, BS 6748:1986
ČSN EN 556-1:2002
ČSN EN ISO 11137:2007

The procedure set out in Annex V, Section 4 of the Directive 93/42/EEC as amended 2007/47/EC was applied for conformity assessment of the products conditions under the supervision of the Notified Body No. 2265 (3EC International, a.s., Slovak republic), certificate no. 2016-MDD/QS-015, issued 30.6. 2016.

Date: 1.7. 2016

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