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Declaration of Conformity

Manufacturer

HertART ApS Gustaf Werners gata 2 SE-421 32 Västra Frölunda Sweden

Product

IVF Pipettes

REF number	Pipette Name
16201	Pasteur Pipette 1 ml
16202	Pasteur Pipette 3 ml

Intended Use

Handling of liquids, media and gametes for in vitro fertilization

Product category

Class IIa according to Rule 2 of the MDD Annex IX

Conformity Assessment Procedure

Annex V coupled with annex VII of Council Directive 93/42/EEC, as amended by Directive 2007/47/EC

Notified Body

BSI NL, Notified Body Number 2797

Attestation

We, the manufacturer, hereby declare that the product IVF Pipettes fulfils the Essential Requirements as stated in Annex I to the Council Directive 93/42/EEC on Medical Devices, as amended by Directive 2007/47/EC.

This Declaration of Conformity is issued under the sole responsibility of HertART ApS.

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Document created by Ann-Catherine Ericson Document reviewed by Document approved by Per Svensson on 2020/05/08 Document QA approved by Lars Ketilsson on 2020/05/14