

Document name: Certificate of Conformity		Issue date: 11-OCT-2019
Form F51-Certificate of Conformity		Revision 004

CERTIFICATE OF CONFORMITY

Product 1712, Follicle Puncture Needle 17G Flush

Lot 201745

Sterilization The products are sterilized by gamma irradiation.

Intended use The products are intended for use in IVF/ART procedures.

The product/lot complies with our minimum quality requirements such as:

MEA $\geq 80\%$ embryo development to blastocyst stage

LAL <20 EU/Device

We declare in own responsibility, that the referenced products meet the General requirements of the guideline 93/42/EEC/Annex I.

All supporting documentation is retained at the premises of the Manufacturer.

Sterility is guaranteed unless the peel pouch is damaged or the product expiry date has expired.

Manufacturer Birr BioSciences B.V.
Bergseweg 4
3633 AK Vreeland, the Netherlands

CE Certificate CE 575680 BSI

Issue date CoC 29-10-2020

Greta Ditzel i.o.
Addy van der Klis
QA&RA Manager

