

Declaration of Conformity

Manufacturer

Vitrolife Sweden AB
Gustaf Werners gata 2
SE 421 32 Västra Frölunda
Sweden

Product

HSA-solution

Intended Use

HSA-solution contains Human Serum Albumin solution (100 mg/mL) and is intended for use in assisted reproductive procedures which include gamete and embryo manipulation. These procedures include the use of HSA-solution as a supplement for culture medium.

Product category

Medical Device in Risk Class III

Attestation

We hereby declare that the product HSA-solution fulfils the Essential Requirements as stated in Annex 1 to the Council Medical Devices Directive 93/42/EEC as amended by 2007/47 EC.

Place and Date

Göteborg on 26 March 2015

Signature



Hans Lehmann
Director QA/QC