



## EU Quality Assurance Certificate (MDR)

Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex XI Part A  
(Systems and Procedure Packs sterilised in accordance with the manufacturer's instructions,  
Article 22(3))

**No. G24 047326 0011 Rev. 00**

**Manufacturer:** **IVF HARTMANN AG**  
Victor-von-Bruns-Strasse 28  
8212 Neuhausen  
SWITZERLAND

**Authorized Representative:** PAUL HARTMANN AG  
Paul-Hartmann-Str. 12, 89522 Heidenheim, GERMANY

The Certification Body of TÜV SÜD Product Service GmbH certifies that the manufacturer has established, documented and implemented a quality management system as described in Article 10 (9) of the Regulation (EU) 2017/745 on medical devices. Details on device categories covered by the quality management system are described on the following page(s). The Report referenced below summarises the result of the assessment and includes reference to relevant CS, harmonized standards and test reports. The conformity assessment has been carried out according to Annex XI Part A of this regulation with a positive result. The involvement of the notified body is limited to the aspects relating to ensuring sterility until the sterile packaging is opened or damaged.

The certified quality assurance system is subject to periodical surveillance by TÜV SÜD Product Service GmbH. All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: [www.tuvsud.com/ps-cert?q=cert:G24 047326 0011 Rev. 00](http://www.tuvsud.com/ps-cert?q=cert:G24 047326 0011 Rev. 00)

**Report No.:** 713180106\_1

**Valid from:** 2020-12-08

**Valid until:** 2025-12-07

Christoph Dicks  
Head of Certification/Notified Body

**Issue date:** 2020-12-08



Benannt durch/Designated by  
Zentralstelle der Länder  
für Gesundheitsschutz  
bei Arzneimitteln und  
Medizinprodukten  
www.zfg.de  
BS-MDR-099



Product Service

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Device Group: MediSet

The validity of this certificate ./.  
depends on conditions and/or  
is limited to the following: