ZERTIFIKAT ◆ CERTIFICATE ◆ 認証証書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Product Service

EC Certificate

EC Design-Examination Certificate

Directive 93/42/EEC on Medical Devices (MDD), Annex II (4)
(Devices in Class III)

No. G7 16 01 86081 005

Manufacturer:

S.A. FILORGA MANUFACTURING
BD Paepsem 18
1070 Anderlecht
BELGIUM

Product:

Soft Tissue Implants
Visco-elastic gel of hyaluronic acid - with lidocaine

The Certification Body of TÜV SÜD Product Service GmbH declares that a design examination has been carried out on the respective devices in accordance with MDD Annex II (4). The design of the devices conforms to the requirements of this Directive. For marketing of these devices an additional Annex II certificate is mandatory. See also notes overleaf.

Report no.: 713056545

Valid from: 2016-01-29
Valid until: 2021-01-28

04052768744029

Date, 2016-01-29

Hans-Heiner Junker

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

TÜV SÜD Product Service GmbH · Zertifizierstelle · Ridlerstraße 65 · 80339 München · Germany

TÜV®

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Model(s):

PFAFUN01V1	Artfiller Universal
PFAFLI01V1	Artfiller Lips
PFAFVO01V1	Artfiller Volume
PFAFFL01V1	Artfiller Fine Lines

Parameters:

- Appearance: Clear, transparent without particles
- pH: 6.5-7.5
- Hydrochloride Lidocaine: 0,27-0,33% DMA <LOQ
- Injectability:
  - 15-25N with TSK 30G 1/2" for Fine Lines
  - 10-20N with TSK 27G 1/2" for Universal
  - 10-20N with TSK 27G 1/2" for Lips
  - and 10-25N with TERUMO 25G 1" for Volume
- Endotoxin content: <0,5 EU/g
- Sterility: Sterile

Facility(ies):

S.A. FILORGA MANUFACTURING
BD Paepsem 18, 1070 Anderlecht, BELGIUM

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