ZERTIFIKAT ◆ CERTIFICATE ◆ 認証書 ◆ 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. G7AO 18 03 10066 417

Manufacturer:

Aesculap AG
Am Aesculap-Platz
78532 Tuttlingen
GERMANY

Product: **Collagen Implants**

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 the directive 93/42/EEC Annex II (4) and Regulation (EU) 722/2012 on medical devices manufactured utilizing tissues of animal origin. The design of the devices conforms to the requirements of the Directive and the Regulation. If a certificate of the European Directorate for the Quality of Medicines (EDQM) has been issued for the respective material of animal origin, the validity of our certificate is associated with the validity of the EDQM certificate. Any changes of the EDQM certificate need to be reported immediately to TÜV SÜD Product Service GmbH by a change notification. For marketing of these devices an additional Annex II without (4) certificate is mandatory. See also notes overleaf.

Report no.: 713117390

Valid from: 2018-05-03
Valid until: 2023-05-02

Date, 2018-05-03

Stefan Preiß

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

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Model(s):

Lyoplant® Onlay
Onlay Dura Mater Substitution from Bovine Collagen, absorbable

Parameters:

Art.-No. (REF)	Size
1067010	2.5 x 2.5 cm
1067020	5.0 x 5.0 cm
1067030	2.5 x 7.5 cm
1067040	7.5 x 7.5 cm
1067050	10.0 x 12.5 cm

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

TÜV®