



EU Technical Documentation Assessment Certificate (MDR)

Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapter II
(Implantable Class IIb Devices and Class III Devices)

No. G70 027023 0176 Rev. 00

Manufacturer: **CROMA-PHARMA GmbH**
Industriezeile 6
2100 Leobendorf
AUSTRIA

SRN Manufacturer - AT-MF-000013284

The Certification Body of TÜV SÜD Product Service GmbH certifies that the manufacturer has drawn up and presented a Technical Documentation according to Annex II and III of the Regulation (EU) 2017/745 on medical devices. Details on devices covered by the Technical Documentation 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 technical documentation assessment included an assessment of the clinical evaluation assessment.

The conformity assessment has been carried out according to Annex IX chapter II of this regulation with a positive result.

Changes to the approved device, where such changes could affect the safety and performance of the device or the conditions prescribed for use of the device, shall require approval from the notified body TÜV SÜD Product Service GmbH.

In order to place the devices on the market with CE-marking, an EU Quality Management System Certificate pursuant to Annex IX chapters I and III is necessary in addition to this EU Technical Documentation Assessment Certificate. 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:G70 027023 0176 Rev. 00](http://www.tuvsud.com/ps-cert?q=cert:G70_027023_0176_Rev.00)

Report No.: 713270059

Valid from: 2023-12-11

Valid until: 2028-12-10

Christoph Dicks
Head of Certification/Notified Body

Issue date: 2023-12-11



EU Technical Documentation Assessment Certificate (MDR)

Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapter II
(Implantable Class IIb Devices and Class III Devices)

No. G70 027023 0176 Rev. 00

Classification: Class III (Annex XVI)
Device Group: P900402 - RESORBABLE FILLING AND RECONSTRUCTION
DEVICES

Basic UDI-DI: 9003502BIMDVOLUME001YQ

Intended Purpose: The intended aesthetic purpose of the viscoelastic implant is to
add volume.

Device(s): Device with non-medical intendend purpose according to article 1
(2)
Pluryal Volume



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



Product Service

EU Technical Documentation Assessment Certificate (MDR)

Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapter II
 (Implantable Class IIb Devices and Class III Devices)

No. G70 027023 0176 Rev. 00

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

Revision History:

Rev.	Dated	Report	Description
00	2023-12-11	713270059	Initial issuance