ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.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 0172 Rev. 01

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, Certification, Validation and Verification Regulations TÜV SÜD Group have to be complied with. For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:G70 027023 0172 Rev. 01

Report No.:	713342326
Preceding Certificate No.:	G70 027023 0172 Rev. 00
Valid from:	2024-09-09
Valid until:	2029-08-21
Date of Initial Issuance:	2023-12-19

Christoph Dicks
Head of Certification/Notified Body

Issue date: 2024-09-09

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123
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Classification:	Class III (Annex XVI)
Device Group:	P900402 - RESORBABLE FILLING AND RECONSTRUCTION DEVICES
Basic UDI-DI:	9003502BIMDVOPLUS00154
Intended Purpose:	The intended aesthetic purpose of the viscoelastic implant is to restore facial volume. Device with non-medical intended purpose according to article 1 (2)
Device(s):	saypha volume plus Lidocaine Beaubella ultra strong Definisse core filler + Lidocaine DERMALSTYLE ultra forte Lidocaine Duraybo ultra strong Faysia ultra forte JALOR Sweet Deep Pluryal Contour Lidocaine Princess VOLUME PLUS Lidocaine Quelvez ultra forte RENNOVA LIFT PLUS LIDO XCELENS EXTREME HV

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

Revision History:

Rev.	Dated	Report	Description	
00	2023-12-19	713263195	Initial issuance	
01	2024-09-09	713342326	Amended: Other	Spelling change of saypha

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