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 109587 0002 Rev. 02

Manufacturer:

Certmedica International GmbH
Magnolienweg 17
63741 Aschaffenburg
GERMANY

SRN Manufacturer - DE-MF-000006199

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 109587 0002 Rev. 02

Report No.: 713275877

Preceding Certificate No.: G70 109587 0002 Rev. 01

Valid from: 2023-05-15
Valid until: 2026-10-07

Date of Initial Issuance: 2021-10-08

Christoph Dicks
Head of Certification/Notified Body

Issue date: 2023-05-15

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123
TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

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No. G70 109587 0002 Rev. 02

Classification:	Class III
Device Group:	G030699 - DEVICES FOR THE NON-SURGICAL TREATMENT OF OBESITY - OTHER
Basic UDI-DI:	426010333L112T4
Intended Purpose:	Lipid binder • for weight reduction • for weight management with LDL cholesterol-lowering accompanying effect
Device(s):	L112 product line - formoline L112 - 500 mg - formoline L112 EXTRA - 750 mg - Sterolsan - 750 mg - formoline - 500 mg

Tablettengewicht	cons. No.	Product REF #	Product Name
Tablet Weight	**Lfd. Nr.**	**Produkt REF #**	**Produktname**
500 mg	1	11-500-04-01	formoline L112
	2	11-500-16-01	formoline L112
	3	11-500-16-02	formoline L112
	4	11-500-16-03	formoline L112
	5	11-500-16-04	formoline L112
	6	11-500-16-05	formoline L112
	7	11-500-16-06	formoline L112

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	8	11-500-16-09	formoline L112
	9	11-500-16-10	formoline L112
	10	11-500-20-01	formoline L112
	11	11-500-20-02	formoline L112
	12	11-500-20-03	formoline L112
	13	11-500-20-04	formoline L112
	14	11-500-20-05	formoline L112
	15	11-500-20-06	formoline L112
	16	35-500-20-03	formoline
750 mg	17	14-750-15-02	formoline L112 EXTRA
	18	14-750-15-03	formoline L112 EXTRA
	19	14-750-15-04	formoline L112 EXTRA
	20	14-750-15-06	formoline L112 EXTRA
	21	14-750-15-08	formoline L112 EXTRA
	22	14-750-16-01	formoline L112 EXTRA
	23	14-750-16-03	formoline L112 EXTRA
	24	14-750-16-04	formoline L112 EXTRA
	25	14-750-16-08	formoline L112 EXTRA
	26	14-750-16-12	formoline L112 EXTRA
750 mg	27	16-750-12-07	Sterolsan

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

Revision History:

Rev.	Dated	Report	Description
00	2021-10-08	713193467	-
01	2022-03-22	713236973	-
02	2023-05-15	713275877	Supplemented: Device(s)/group of device(s) added

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