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. 03

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, 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 109587 0002 Rev. 03

Report No.:	713344132
Preceding Certificate No.:	G70 109587 0002 Rev. 02
Valid from:	2024-12-11
Valid until:	2026-10-07
Date of Initial Issuance:	2021-10-08

Issue date: 2024-12-11

Christoph Dicks
Head of Certification/Notified Body

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

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Device(s):

L112 product line
- formoline L112 - 500 mg
- formoline - 500 mg
- formoline L112 EXTRA - 750 mg
- Sterolsan - 750 mg
- formoline EXTRA - 750 mg
- Liporeform protect - 750 mg

Tablet Weight Tablettengewicht	cons. No. Lfd. Nr.	Product REF # Produkt REF #	Product Name 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
	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

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Tablet Weight Tablettengewicht	cons. No. Lfd. Nr.	Product REF # Produkt REF #	Product Name Produktname
500 mg	16	35-500-16-01	formoline
	17	35-500-16-02	formoline
	18	35-500-16-03	formoline
	19	35-500-16-04	formoline
	20	35-500-16-05	formoline
	21	35-500-16-06	formoline
	22	35-500-20-01	formoline
	23	35-500-20-02	formoline
	24	35-500-20-03	formoline
	25	35-500-20-04	formoline
	26	35-500-20-05	formoline
	27	35-500-20-06	formoline

Tablet Weight Tablettengewicht	cons. No. Lfd. Nr.	Product REF # Produkt REF #	Product Name Produktname
750 mg	28	14-750-04-01	formoline L112 EXTRA
	29	14-750-15-02	formoline L112 EXTRA
	30	14-750-15-03	formoline L112 EXTRA
	31	14-750-15-04	formoline L112 EXTRA
	32	14-750-15-06	formoline L112 EXTRA
	33	14-750-15-08	formoline L112 EXTRA
	34	14-750-16-01	formoline L112 EXTRA
	35	14-750-16-03	formoline L112 EXTRA
	36	14-750-16-04	formoline L112 EXTRA
	37	14-750-16-08	formoline L112 EXTRA
	38	14-750-16-12	formoline L112 EXTRA

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Tablet Weight Tablettengewicht	cons. No. Lfd. Nr.	Product REF # Produkt REF #	Product Name Produktname
750 mg	39	38-750-15-01	formoline EXTRA
	40	38-750-15-02	formoline EXTRA
	41	38-750-15-03	formoline EXTRA
	42	38-750-15-04	formoline EXTRA
	43	38-750-15-05	formoline EXTRA
	44	38-750-15-06	formoline EXTRA
	45	38-750-15-07	formoline EXTRA
	46	38-750-16-01	formoline EXTRA
	47	38-750-16-02	formoline EXTRA
	48	38-750-16-03	formoline EXTRA
	49	38-750-16-04	formoline EXTRA
	50	38-750-16-05	formoline EXTRA
	51	38-750-16-06	formoline EXTRA
750 mg	52	16-750-12-07	Sterolsan
750 mg	53	39-750-04-01	Liporeform protect
	54	39-750-15-01	Liporeform protect
	55	39-750-15-02	Liporeform protect
	56	39-750-15-03	Liporeform protect
	57	39-750-15-04	Liporeform protect
	58	39-750-15-08	Liporeform protect
	59	39-750-15-10	Liporeform protect
	60	39-750-15-12	Liporeform protect

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
03	2024-12-11	713344132	Supplemented: Device(s)/group of device(s) added

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