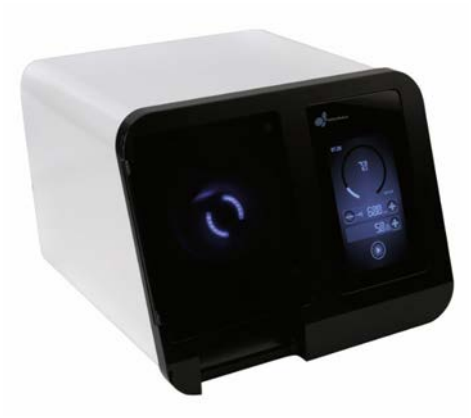
Liposat® Pro



CE0482
Clase IIb

Descripción:

- La bomba de infiltración de anestesia local TLA,
- Dimensiones 275 x 210 x 350 mm
- Peso 5,8 kg
- Velocidad de bombeo regulable de 50 - 300 ml/min
- Dispositivo médico clase IIb
- Precisión de la velocidad de bombeo ±15%
- Fuente de alimentación 100 - 240 VCA, 50 - 60 Hz
- Clase del dispositivo médico IIb.

Comodidad:

- Tecnología de parada automática que se activa cuando se alcanza el volumen objetivo.
- Cargador automático de juegos de tubos
- Pedal (interruptor de pie)
- Agiliza y simplifica el flujo de trabajo de la operación
- Diseñada para adaptarse a las estaciones de trabajo Workstation con bandejas calefactoras para el suero anestésico.
- Gracias a su innovadora tecnología de aislamiento, también es el mejor de su clase en términos de nivel de sonido, funcionando de la manera más silenciosa posible.

Aplicaciones:

- Infiltraciones pequeñas y grandes
- Liposucción
- Extracción de venas
- Succión de glándulas sudoríparas
- y otros

Datos Técnicos	
Dimensiones	275 x 210 x 350mm
Peso	5,8 Kg.
Velocidad	50 – 300 ml/minuto.
Precisión de la velocidad de bombeo	±15%
Fuente de alimentación	100 - 240 VCA, 50 - 60 Hz
Clase del dispositivo médico	IIb

Möller Medical GmbH

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E-Mail: info@moeller-medical.com · Web: www.moeller-medical.com

MÖLLER

KONFORMITÄTSERKLÄRUNG / DECLARATION OF CONFORMITY

Name und Adresse des Herstellers / Name and address of the manufacturer	**Möller Medical GmbH** Wasserkuppenstraße 29-31 36043 Fulda, Germany
Einmalige Registrierungsnummer / Single Registration Number (SRN)	**DE-MF-000005100**

Wir tragen die alleinige Verantwortung für die Ausstellung dieser EU-Konformitätserklärung. / We are solely responsible for issuing this EU Declaration of Conformity.

Produktname/n / Product name/s	**Liposat Pro**	**REF. 00003977**
	Liposat Pro plus	**REF. 00003974**
Basis-UDI-DI / Basic UDI-DI	**426027717MM.002WB**	
Klassifizierung / Classification	**IIb** Nach Anhang VIII der Verordnung 2017/745 / acc. to annex VIII of regulation 2017/745	

Wir versichern, dass das hier erfasste Produkt der VERORDNUNG (EU) 2017/745 und den weiteren einschlägigen Rechtsvorschriften der EU entspricht. / We assure that the product covered here complies with REGULATION (EU) 2017/745 and other relevant EU legislation.

Gemeinsame Spezifikationen (GS), für die die Konformität erklärt wird / Common Specifications (CS) for which conformity is declared	**Not available**
Konformitätsbewertungsverfahren / Conformity assessment procedure	**MDR 2017/745** Annex IX Chapter 1
Zertifikatsnummer / Certificate No.	**7295GB448220906**
Generische Produktgruppe / Generic Product Group	**Z12040214** Liposuction Units
Konformitätsbewertungsstelle (falls beigezogen) / Notified Body (if consulted)	**MedCert GmbH** CE 0482 Pilatuspool 2 20355 Hamburg

Fulda, 02. January 2023
Ort, Datum / Place, date

Andreas Bacher, Managing Director
Name und Funktion / Name and function

Gültig bis 22. April 2026 / Valid until 22. April 2026

CONFIDENTIAL

EU Quality Management System Certificate

The Notified Body

MEDCERT Zertifizierungs- und Prüfungsgesellschaft für die Medizin GmbH
Pilatuspool 2 – 20355 Hamburg – Germany

herewith certifies that the company

Möller Medical GmbH
Wasserkuppenstrasse 29-31
36043 Fulda
Germany

SRN: DE-MF-000005100

with locations listed in the appendix

has introduced, applies and maintains a quality management system for the medical devices/groups of medical devices listed in the appendix.

The compliance of this quality management system to the requirements of the **Regulation (EU) 2017/745 on medical devices** was verified by assessment according to:

Annex IX Chapter I

Any applicable limitations of this certification for certain medical devices are included in the appendix. This certification is subject to surveillance by MEDCERT.

Effective date:	**2021-10-19**
Expiry date:	**2026-04-22**
Final assessment report No.:	7295IA09F
Procedure No.:	QS – 7295
Certificate No.:	7295GB448211019
Preceding certificate No.:	–
Preceding certificate date:	–
Identification of changes:	–

Hamburg, 2021-10-19

MEDCERT Certification Body
Lorenz Runge

The certificate is only valid when provided entirely with all of its pages.
To verify the validity of this certificate, contact info@medcert.de.

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
BS-MDR-096

MEDCERT Notified Body Identification Number: 0482

MED CERT®

Certification. Medical Only.

Appendix of EU Quality Management System Certificate

Procedure No.: QS – 7295
Certificate No.: 7295GB448211019

Locations included in the scope of certificate

Wasserkuppenstrasse 29-31
36043 Fulda
Germany

This appendix is integral part of the above-referenced certificate.
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Appendix of EU Quality Management System Certificate

Procedure No.: QS – 7295
Certificate No.: 7295GB448211019

Class IIa medical devices

Category	EMDN code	Medical devices/groups of medical devices
MDA 0306	**Z12040214**	Liposuction units
	A018099	Needles - other accessories
MDN 1202	**A010201**	Needles and kits - histologic and cytologic biopsy of small tissues
	A018003	Needle introducers
	A019011	Needles - bone infusion and vertebroplastic
	Z12040214	Liposuction units

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Appendix of EU Quality Management System Certificate

Procedure No.: QS – 7295
Certificate No.: 7295GB448211019

Class IIb medical devices

Category	EMDN code	Medical devices/groups of medical devices
MDA 0306	**Z12040214**	Liposuction units Intended purpose: Use for medical indications, including those accompanied by a change in fatty tissue, and for aesthetic body contouring / Administer tumescent local anaesthesia, other aqueous infusion solutions, as well as endogenous subcutaneous tissue and its components, into the body

This appendix is integral part of the above-referenced certificate.
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MEDCERT Notified Body Identification Number: 0482

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