

Liposat® Pro Plus · tecnología inteligente

Descripción:

- Bomba de infiltración de anestesia local TLA & infiltración de grasa autóloga, especial lipotransferencia.
- Dimensiones 275 x 210 x 350 mm
- Peso 6 kg
- Velocidad de bombeo regulable de 50 – 1.000 ml/min
- Dispositivo médico clase IIb
- Precisión de la velocidad de bombeo $\pm 15\%$
- Fuente de alimentación 100 - 240 VCA, 50 - 60 Hz

Comodidad:

- Maneje con suavidad y precisión las células grasas.
- Maximizar la viabilidad de las células grasas.
- 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.

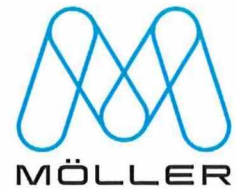
Aplicaciones:

- Infiltración TLA para volúmenes pequeños y grandes
- Liposucción
- Extracción de venas
- Succión de glándulas sudoríparas
- Infiltración de grasa para volúmenes pequeños y grandes, Mano, cara, Levantamiento de glúteos brasileño, mamá y otros



CE0482
Clase IIb

Datos Técnicos	
Dimensiones	275 x 210 x 350mm
Peso	6 Kg.
Velocidad	50 – 1.000 ml/minuto.
Precisión de la velocidad de bombeo	$\pm 15\%$
Fuente de alimentación	100 - 240 VCA, 50 - 60 Hz
Clase del dispositivo médico	IIb



KONFORMITÄTSERKLÄRUNG / DECLARATION OF CONFORMITY

Name und Adresse des Herstellers / **Möller Medical GmbH**
Name and address of the manufacturer Wasserkuppenstraße 29-31
36043 Fulda, Germany

Einmalige Registrierungsnummer / **DE-MF-000005100**
Single Registration Number (SRN)

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 **Ib**
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 / **MDR 2017/745**
Conformity assessment procedure Annex IX Chapter 1

Zertifikatsnummer / Certificate No. **7295GB448220906**

Generische Produktgruppe / Generic Product Group **Z12040214 Liposuction Units**

Konformitätsbewertungsstelle (falls beigezogen) / **MedCert GmbH CE 0482**
Notified Body (if consulted) 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.

MEDCERT Notified Body Identification Number: 0482



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

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