

Liposuctor Vacusat® Power

Descripción:

- Liposuctor Vacusat® Power, lipoaspirador quirúrgico con protección contra desbordamiento y filtro hidrófobo.
- Tecnología de vacío palas rotativas de grafito.
- Proporciona un vacío. -90 kPa en NN (normal nulo; 100 kPa = 1 Bar = 1.000 mbar)
- Potencia de aspiración 58l/min +- 6 l/min a 50 Hz
- Volumen acústico de 53 dB(A)
- Clase de dispositivo médico: IIa

Comodidad:

- Montaje enrollable y compacto
- Agiliza y simplifica el flujo de trabajo de la operación
- Diseñado como carro para todos los dispositivos incluidos en la estación de Trabajo:
Vibrasat Pro, Lipoescultor · PAL System, (ref: 00003920)
Liposat Pro, Bomba de infiltración de suero TLA (ref: 00003977)
Liposat Pro, Plus Bomba de infiltración de suero y grasa. (ref: 00003974)
Thermia Pro, bandejas calefactoras para el suero anestésico. (ref:00004253)
- 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:

- Succión de grasa y fluidos corporales
- Liposucción
- Tratamientos de lipedema

Accesorios incluidos:

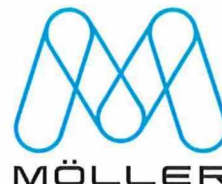
- Pedal neumático
- Tubo de conexión de vacío
- Tubo de serie
- Tubo serie de vacío
- 2 abrazaderas de riel
- 2 contenedores de 3000cc
- 2 Bolsas recolectoras desechables
- 1 Contenedor Protector contra desbordamiento
- 1 Filtro Hidrofóbico
- 10 Láminas de filtro bacteriano
- 1 Cable conexión red eléctrica 220v.



Vacusat Power
Referencia: 00002252

Datos técnicos

Dimensiones	1000 x 500 x 560 mm
Peso	26 kg
Potencia de succión	58 l/min ± 6 l/min at 50 Hz
Clase de dispositivo médico Vacío	IIa
Fuente de alimentación	-90 kPa on NN (normal null; 100 kPa = 1 Bar = 1,000 mbar)
Consumo de corriente Fusible	100 - 240 VAC, 50 - 60 Hz
Volumen acústico	53 dB(A)
Consumo de corriente 1,1 A	1.1 A
Fusible	T 1.6 A H



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 **Vacusat Power** **REF. 00002252**

Basis-UDI-DI / Basic UDI-DI **426027717MM.003WD**

Klassifizierung / Classification **Ila**
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

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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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