

Lot 19 Aspirator toracal, F-40.00, Fazzini, Italia

<i>Parametri solicitați</i>	<i>Parametri oferiți</i>
Aspirator toracal Cod 130310 Descriere Aspirator toracic asigură aspirarea și evacuarea fluidelor corporale și/sau de aer care se pot acumula între plămâni și peretele toracic (spațiul pleural), după o intervenție chirurgicală toracică, penetrare a rănilor de pe piept, barotraumă, ruptură traheală, bronșită sau ca urmare a unei boli sau unor defecte congenitale. Parametru Specificația Sistemul vacuum Limita maximă ≥ 550 mmHg Indicator de presiune da Debitul de aer ≥ 25 l/min Nivelul de zgomot < 65 dB Vas colector Protecție la umplere da Capacitatea ≥ 1000 ml Reutilizabil da Tip Filtru Unică utilizare da Tensiunea de alimentare 220 V, 50 Hz Accesorii Filtru antibacterian de unică utilizare 15 buc. Vas colector Reutilizabil 1 buc.	Aspirator toracal Cod 130310 Descriere Aspirator toracic asigură aspirarea și evacuarea fluidelor corporale și/sau de aer care se pot acumula între plămâni și peretele toracic (spațiul pleural), după o intervenție chirurgicală toracică, penetrare a rănilor de pe piept, barotraumă, ruptură traheală, bronșită sau ca urmare a unei boli sau unor defecte congenitale. Parametru Specificația Sistemul vacuum Limita maximă 0,80 - 600 mmHg Indicator de presiune da Debitul de aer 32 l/min Nivelul de zgomot 62,8 dB Vas colector Protecție la umplere da Capacitatea ≥ 1000 ml Reutilizabil da Tip Filtru Unică utilizare da Tensiunea de alimentare 230 V, 50-60 Hz Accesorii Filtru antibacterian de unică utilizare 15 buc. Vas colector Reutilizabil 1 buc.

Lot 21 Aspirator chirurgical portabil F-60B, Fazzini, Italia

<i>Parametri solicitați</i>	<i>Parametri oferiți</i>
Aspirator chirurgical portabil (caracteristici de baza) Cod 130330 Descriere Aspiratoarele chirurgicale sunt capabile să creeze o presiune de vid > 600 mm Hg. Cele mai multe proceduri chirurgicale necesită aspirare pentru a elimina sângele și lichidele care se acumulează în zona operatorie și obstrucționează vizibilitatea chirurgului. Parametru Specificația Vacuum Limita maximă ≥ 600 mm Hg Rata de flux, l/min. 25-40 Indicator vacuum da, eroarea $\geq \pm 10\%$ Reglator aspirație da Nivelul de zgomot, dBA ≤ 65 dBA Vas colector Material excepție sticla Numărul ≥ 1 buc. Capacitatea, L ≥ 2 L Protecție la umplere da Vas tip reutilizabil da Aspirator mobil pe suport cu roțile ≥ 4 roți Roți cu frână da, ≥ 2 buc. Tensiunea de alimentare 220 V, 50 Hz Baterie internă reutilizabilă da Timp operare > 1 h Filtru de unică utilizare 15 buc.	Aspirator chirurgical portabil (caracteristici de baza) Cod 130330 Descriere Aspiratoarele chirurgicale sunt capabile să creeze o presiune de vid > 600 mm Hg. Cele mai multe proceduri chirurgicale necesită aspirare pentru a elimina sângele și lichidele care se acumulează în zona operatorie și obstrucționează vizibilitatea chirurgului. Parametru Specificația Vacuum Limita maximă 0,80 bar - 600 mm Hg Rata de flux, l/min. 60 Indicator vacuum da, eroarea $\geq \pm 10\%$ Reglator aspirație da Nivelul de zgomot, dBA $\leq 61,1$ dBA Vas colector Material – MAKROLON AUTOCLAVABLE Numărul 2 buc. Capacitatea, L - 2 L Protecție la umplere da Vas tip reutilizabil da Aspirator mobil pe suport cu roțile 4 roți Roți cu frână da, 2 buc. Tensiunea de alimentare 230 V, 50-60 Hz Baterie internă reutilizabilă da Timp operare min 60 min Filtru de unică utilizare 15 buc.

A



Product Service

Audit Plan

Version 0
Order no.: ITA 1691847

1 Audit Overview

Type of Audit	☐ Stage 1 ☐ Stage 2 ☐ Stage 1 + Stage 2 ☐ Re-Certification ☐ 1st Surveillance ☐ 2nd Surveillance ☐ Surveillance 1 Remote A ☐ Surveillance 2 Remote A ☒ Recertification Remote A ☐ Surveillance 1 Remote A2 ☐ Surveillance 2 Remote A2 ☐ Recertification Remote A2 ☐ Surveillance 1 Follow-up B ☐ Surveillance 2 Follow-up B ☐ Recertification Follow-up B ☐ Early Recertification (Post-Part A) ☐ Special Audit Type: _____
Additional Type of Audit	☐ Scope Expansion QMS (Products / Processes / Facilities) ☐ Scope Expansion Regulatory (Products / Processes / Facilities) ☐ Upgrade / change QMS Standard ☐ Other: _____
Audit criteria	☒ (DIN) EN ISO 13485:2016 ☒ ISO 13485:2016 ☐ Taiwan GMP ☐ (DIN) EN ISO 9001:2015 ☒ ISO 9001:2015 ☐ Other: _____ ☐ Defined processes and documentation of the auditee's Quality Management System - European Directives: ☒ Council Directives 93/42/EEC (MDD) – annex II (w/o 4) ☒ Council Directives 93/42/EEC (MDD) – annex V ☒ Council Directives 93/42/EEC (MDD) – annex VI ☐ Council Directives 90/385/EEC (AIMDD) – annex 2 (w/o 4) ☐ Council Directives 98/79/EC (IVDD) – annex IV ☐ Council Directives 98/79/EC (IVDD).– annex VII
Audit period (on site)	28/04/2021 - 29/04/2021
Auditee (s) / Location(s)	FAZZINI S.r.l., SS Padana Sup. 317, 20090 Vimodrone (MI), Italy (44963)
Audit Responsible	Daniele Dipinto
Lead Auditor / Auditor	Roberto Gabriotti (RG)/
Expert / Trainee	None



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Auditor Reg. No. (Mainland China only)	None
Translator / Observer and their organization	None
QM Manual: Revision / Date	Current version
Audit Language	Italian
First release of Audit Plan / Date	2021-04-01

1.1 Audit Objectives

The objectives of this Audit are:

- Determine conformance of the Management System with the Audit Criteria (see above)
- Evaluate the effectiveness of the Management System in meeting its specified quality objectives
- Evaluate the capability of the Management System to ensure compliance with relevant statutory, regulatory and contractual requirements (as applicable)
- Evaluate the effectiveness of the Management System to ensure that agreed requirements for products and/or services are met
- Identify areas for potential improvement of the Management System
- Evaluate the effectiveness of the corrective actions related to the Nonconformities and Minor Nonconformities of the previous Audit (if applicable)
-

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2 Audit Program(s)

- The completion of the audit program(s) and the fulfilment of code requirements shall be in accordance with **MED W 09.16**, including the limitations for use of QMS auditors.
- If the audit is related to **MED W 09.46**, then the clause coverage related to the combination of the Part A and Part B audit should be entered into the audit being replaced by the **MED W 09.46** approach.
- A separate audit program should be completed for all audits within the three-year cycle for each site and scheme included in the audit. If a scheme is not applicable, then the associated audit program can be deleted.
- For (DIN EN) ISO 13485:2016 / EC-Directives / EU Regulation and the ISO 9001:2015 Audit Programs:
 - Recertification/Initial Audit after 6/20/2020: If an "X" is in the "Every S", then clause must be audited every surveillance and if an "M" is in "Every S", then the clause must be audited every surveillance in a joint audit with MDSAP.
 - Recertification/Initial Audit prior to 6/20/2020: The existing audit program can be followed by transposing the details to the tables below. For convenience, clauses that were required in the prior versions of the audit plan are marked with grey columns.

2.1 (DIN EN) ISO 13485:2016 / EC-Directives / EU Regulation

Planning according to (DIN EN) ISO 13485:2016 / EC-Directives / EU Regulation per Location: 1																															
Clauses	4	5	6					1	2		3										4			5							
			1	2	3	4	1		2	3	1	2	3	4	5	6	7	8	9	10	1	2	3	1	2	3	4	5	6	7	8
Cert / Recert	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Every S	X	X		M			X		M	M									M		M										
S1	X	X	X	X			X	X	X												X	X	X	X	X	X	X	X	X	X	X
S2	X	X	X		X		X	X	X	X	X	X	X	X	X	X	X	X	X				X								X

Clauses	7			6	1	2						3				4	5		
	9	10	11			1	2	3	4	5	6	1	2	3	4		1	2	3
Cert / Recert	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Every S	M				X	X	M	X	X	X			M	X	X	X	X	X	X
S1	X	X	X		X	X	X	X	X	X						X	X	X	X
S2	X			X	X	X		X	X	X	X	X	X	X	X	X	X	X	X

Cycle	EA Code(s)	MD / IVD Code(s)	MDS Code(s)
Cert / Recert	19, 29a (Technical Areas – applicable only for TUV Italia: 1.1.A, 1.2.A e 1.2.C)	MD / IVD-code(s): MD 0101_2_3 (OEM), MD1302 (OEM); MD 1102, MD 1104_1; EA 19, 29a (Technical Areas – applicable only for TUV Italia: 1.1.A, 1.2.A e 1.2.C)	NA
S1	19, 29a (Technical Areas – applicable only for TUV Italia: 1.2.A e 1.2.C)	MD / IVD-code(s): MD1302 (OEM); MD 1102, MD 1104_1, MD 1301 (class Im)	NA
S2	29a (Technical Areas – applicable only for TUV Italia: 1.1.A.)	MD / IVD-code(s): MD 0101_2_3 (OEM), MD 0104 (OEM, class Im)	NA

If multiple site, note site specific differences for codes or process:

Cycle	MDT/IVT Code(s)	MDS/IVS Code(s)	MDA/MDN/IVR Code(s)	IVP/IVD Code(s)
Cert / Recert	NA	NA	NA	NA
S1	NA	NA	NA	NA
S2	NA	NA	NA	NA

If multiple site, note site specific differences for codes or process:

* „M“ signifies that the clause must be audited every surveillance when the audit is a joint audit with MDSAP

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3 Audit Plan

- Within the Audit Scope, include the applicable ISO clauses, process name, task name (MDSAP only), and task number (MDSAP only). If regulations or directives are applicable, then explicitly document their coverage in the plan.
- If more than one site is being audited, it shall be clearly documented which site is being addressed in each element listed in the audit plan.
- If the audit is conducted remotely and/or utilizes ICT technology, then the specific tools used (e.g. WebEx, Adobe Connect, e-mail, teleconference) within each process must be detailed.

Date / Time Auditor, Expert, Trainee	Function / Unit / Location	Audit Scope (Process)	Participants Auditees
2021-04-28	FAZZINI Headquarter - REMOTE		
09:00-09:30 RG	Direction, Quality Virtual Room A	Opening meeting QS scope confirmation Changes from last audit Overview on main processes and critical supplier	Direction QS manager
9.30-10.30 RG	Direction QS dept. Virtual Room A	Direction Processes (#5, #6.1, # 8.1, #8.2.5, #8.5.1) Including specific requirements ISO 9001:2015 (risk and opportunities, interested parts and context analysis)	CEO QS manager
10.30-11.30 RG	QS dept. Virtual Room A	Quality Management system (#4), use of the logo certification, QS change, validation of software used in QMS	QS manager
11.00-13.00 RG	QS dept. Virtual Room A	QS monitoring process: customer complaints and PMS (#8.2.1, #8.2.2), internal audits (#8.2.4), Vigilance/recall (#8.2.3, 8.3.3), NC (#8.3.1, #8.3.2) and CAPAs (#8.5.2, #8.5.3)	QS manager
13:00-14:00		Lunch Break	
14.00-15.00 RG	Direction, Quality Virtual Room A	Review findings from previous audit	Direction QS manager
15.00-17.00 RG	R&D dept. Virtual Room A	R&D process (#7.3) including design transfer and changes [active medical devices: MD1302 (OEM); MD 1102, MD 1104_1, MD 1301 (class Im)]	R&D manager, staff
17.00-18.00 RG	QS dept. Virtual Room A	EC Directive requirements	QS manager
2021-04-29			



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09.00-10.00 RG	Commercial dept. Virtual Room A	Commercial dept. including customer satisfaction and distribution process (#7.2)	Commercial manager, staff
10.00-11.00 RC	HR dept. Virtual Room A	Human resources (#6.2)	HR manager, staff
11.00.-12.00 RC	Purchasing dept. Virtual Room A	Purchasing dept. (#7.4) including control of OEM suppliers	Purchasing manager, staff
12.00-12.30 RC	QS dept. Virtual Room A	Control of outsourcing (#4.1.5)	QS manager
12.30-13.00 RG		Auditor's preparation	
13.00-14.00		Lunch Break	
14.00-14.55 RG	Direction, QS dept. Virtual Room A	Closure meeting	CEO QS manager
14.55	Direction, QS dept. Virtual Room A	END OF THE AUDIT	CEO QS manager

A room for the Audit Team should be provided to ensure undisturbed communication as well as safe keeping of documents. The Auditors are accompanied by the Audit responsible during the Audit. The Audit Plan can be adjusted during the Audit. Opening and closing meeting are fixed.

Please note: The company and the Lead Auditor should discuss any personal protective equipment needed for the Audit well in advance before the start of the Audit. Protective equipment (helmet, safety shoes, safety goggles, cleanroom clothes) must be provided by the audited company.

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4 Signatures

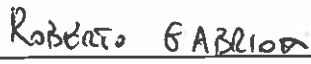
The parties agree that the contract shall be concluded in text form. To comply with this requirement any transmission using telecommunication means (e.g. via letter, fax, e-mail) and a simple signature (e.g. by electronic signature with Adobe Sign) is sufficient.

The complete audit plan record may consist of two documents: (1) The audit plan signed by the audit team and client prior to the audit, Sections 4.1 and 4.2; (2) The audit plan signed by the lead auditor after the audit, Section 4.3.

4.1 Audit Team (Prior to the Opening Meeting)

- We have read, understood and accepted the "Independence, Impartiality, Conflict of Interest and Confidentiality Requirements" procedure [MED P 09.09](#).
- To the best of our knowledge we hereby declare that we are independent, impartial and objective in respect of this project and have no conflict of interest.
- Lead Auditor: I confirm that the Audit Plan is released prior to the Audit.

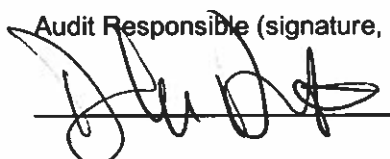
Auditor(s) / Expert(s) / Trainee (signature, date)

4.2 Client (Prior to the Opening Meeting)

- We confirm that Quality Management System certification marks are not used in any advertising that implies that they apply to products.
- We confirm that this Audit Plan including Audit objectives are accepted.
- We confirm that the Auditors / Experts / Translator are accepted.
 - Including the fact that the following person(s) is/are employed by the local TÜV SÜD Product Service company: None
 - Including the fact that the following person(s) is/are not employed within the TÜV SÜD Group: Roberto Gabriotti
- We confirm that we have the necessary infrastructure to support the Information and Communication Technology (ICT) proposed within the audit program and approve the use of ICT.

Audit Responsible (signature, date)

 2021-04-28

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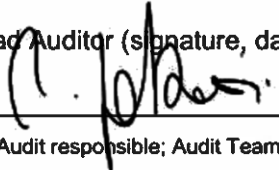
4.3 Lead Auditor (Prior to Closing Meeting)

The audit has been performed as documented within this audit plan.

Based on the objective evidence, the Audit Team confirms that the Audit objectives have been met. The Audit Team concludes that the company's Quality Management System

- ☒ Conforms with the Audit criteria as specified above
- ☐ Does not fully conform with the Audit criteria as specified above.
The Audit Team did identify nonconformities
Refer to See **Findings List** for more details including follow-up actions
- ☐ Re-Certification Audit:
The Audit results from the last three (3) years were considered for both the Audit planning and the current conclusion for this recertification

Lead Auditor (signature, date):

 2021-04-29

cc: Audit responsible; Audit Team members, Certification Body



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5 Version History

Rev. No.	Date (yyyy-mm-dd)	Name	Description of Change
0	2021-04-01	Riccardo Cottone	Creation of report
1			



FAZZINI

Your Health is Our Aim



Company Profile

Profil de la société



Fazzini, your trusted partner

Since 1995, company Fazzini manufactures and distributes internationally medical equipment essential for the activity of health facilities in the private or public sectors. Located near Milan in Italy, Fazzini offers more than 3000 references of furniture and medical devices covering the world of primary and secondary care, the technical platform and hospitalization.

Fazzini, votre partenaire de confiance

Depuis 1995, la société Fazzini fabrique et distribue à l'international les équipements médicaux essentiels à l'activité des établissements de santé dans les secteurs privés ou publics. Installée près de Milan en Italie, Fazzini propose plus de 3000 références de mobilier et dispositifs médicaux couvrant les univers des soins primaires et secondaires, du plateau technique et de l'hospitalisation.

TOYOTA
TSUSHO
CORPORATION

Toyota Tsusho is a present distribution company in Japan and over 60 countries worldwide through more than 500 subsidiaries.

Toyota Tsusho est une société de distribution présente au Japon et dans plus de 60 pays dans le monde à travers plus de 500 filiales.

CFAO

CFAO is a leader in specialized distribution, privileged partner of major international brands, addressing the high-potential markets in Africa and the Communities and Territories overseas territories.

CFAO est un leader de la distribution spécialisée, partenaire privilégié des grandes marques internationales, s'adressant à des marchés à fort potentiel en Afrique et dans les Collectivités et Territoires d'Outre-Mer.

EURAPHARMA

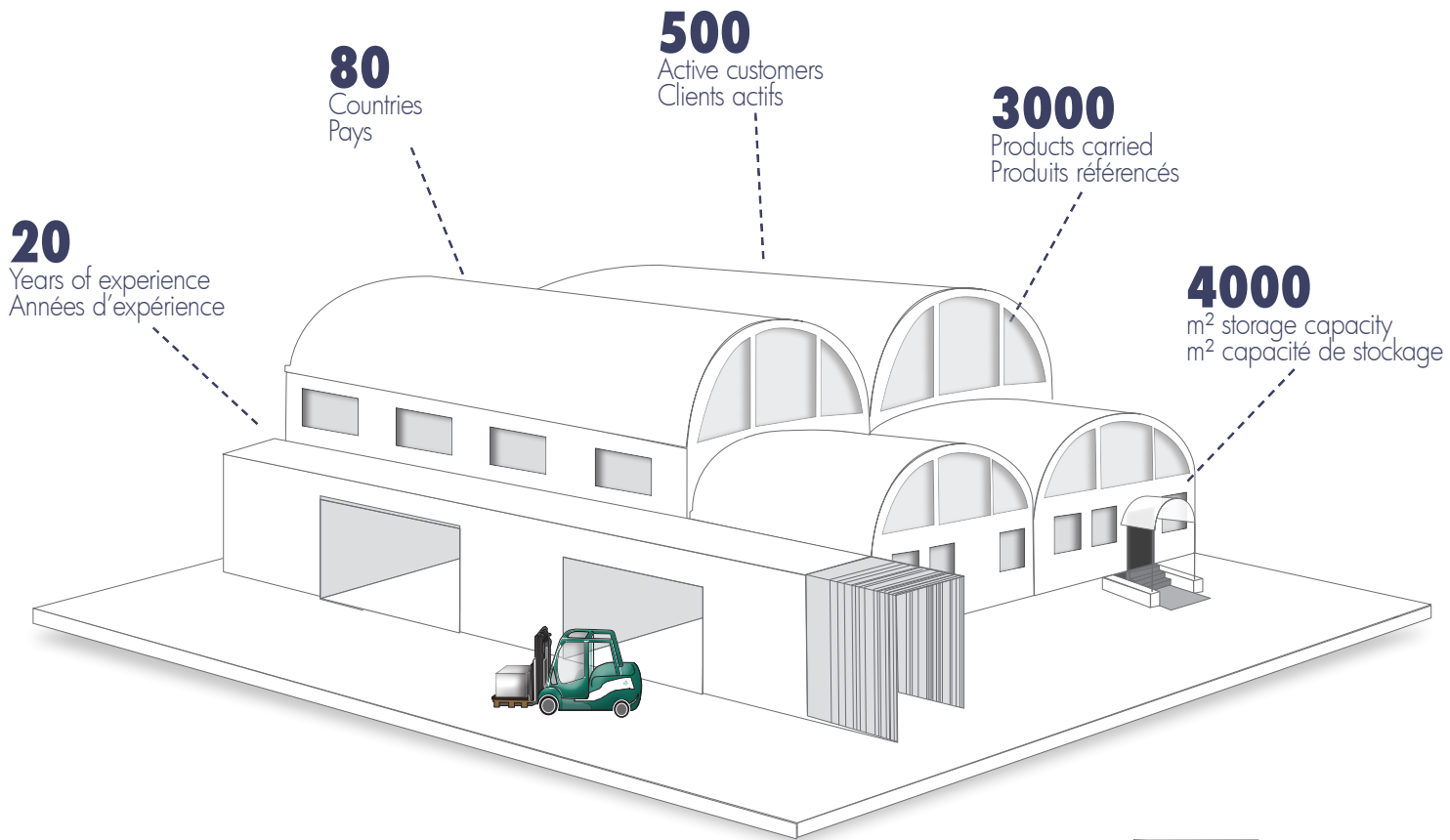
Eurapharma among the leading distributors of pharmaceutical products and services in Africa and the Communities and Territories overseas territories.

Eurapharma compte parmi les leaders de la distribution de produits et services pharmaceutiques en Afrique et dans les Collectivités et Territoires d'Outre-Mer.

FAZZINI

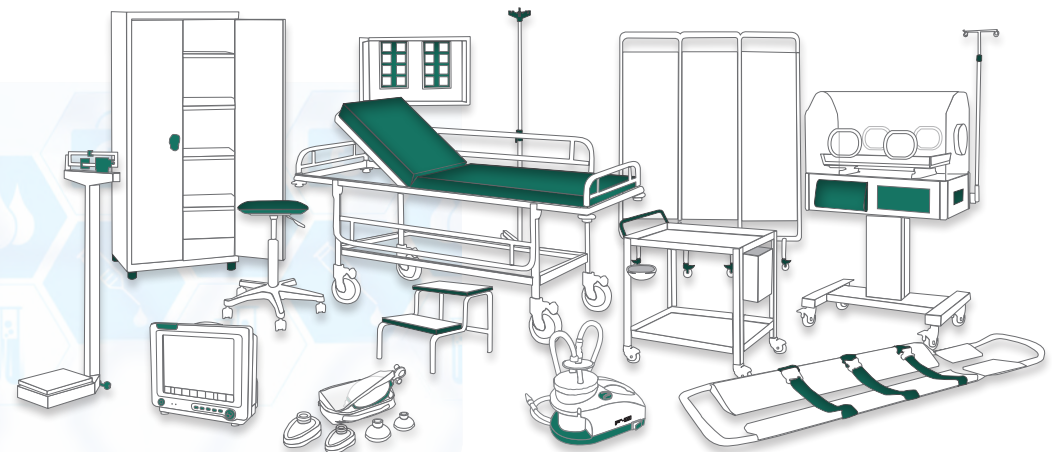
Fazzini manufactures and distributes internationally medical equipment essential for the activity of health facilities in the private or public sectors.

Fazzini fabrique et distribue à l'international les équipements médicaux essentiels à l'activité des établissements de santé dans les secteurs privés ou publics.



« Fazzini is driven by the strong desire to offer more access to comprehensive and affordable range of quality products »

« Fazzini est animée par la forte volonté d'offrir au plus grand nombre l'accès à une gamme complète et abordable de produits de qualité. »



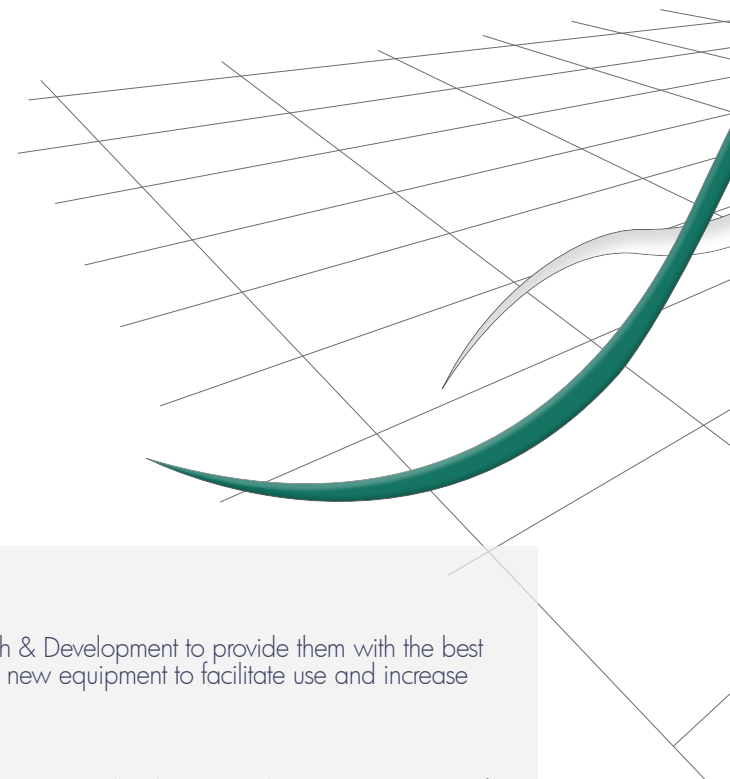


Always improving

We constantly work to offer you the best balance to allow as many of you access to quality products.

Innovant et perfectionnant

Nous travaillons perpétuellement à vous proposer le meilleur équilibre afin de permettre au plus grand nombre d'entre vous l'accès à des produits de qualité.

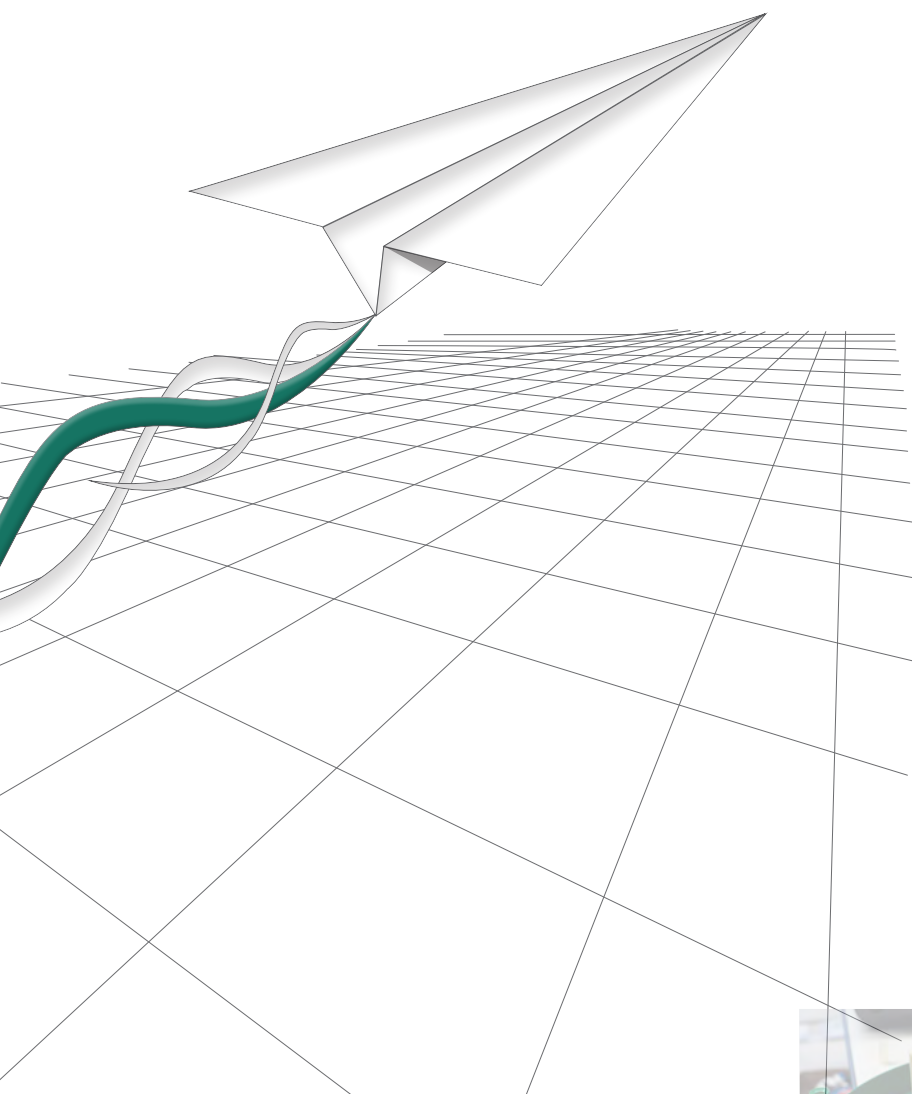


Research & Development

Exercise stresses for health professionals require very reactive Research & Development to provide them with the best solutions. Our research today is through the constant development of new equipment to facilitate use and increase operational condition duration.

Recherche & Développement

Les contraintes d'exercice des professionnels de santé nécessitent un service Recherche & Développement très réactif afin de leur apporter les solutions les plus adaptées. Notre recherche passe aujourd'hui par le développement constant de nouveaux équipements pour en faciliter l'utilisation et accroître leur durée de condition opérationnelle.

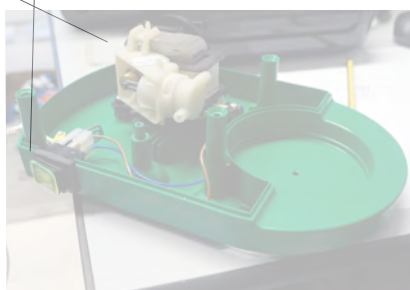


Production

A large part of the range is produced in Italy and benefits of a 1 year warranty.

Production

Une grande partie de notre gamme est produite en Italie et elle bénéficie d'une garantie d'un an.





Turn-key solutions

Because every client is unique, we tailor our offer to your needs. Fazzini has created a comprehensive range of solutions to integrate the complexity and diversity of needs expressed.

Services intégrés

Parce que chaque client est unique, nous adaptons notre proposition à votre besoin. Fazzini a créé une offre complète de solutions permettant d'intégrer la complexité et la diversité des besoins exprimés.

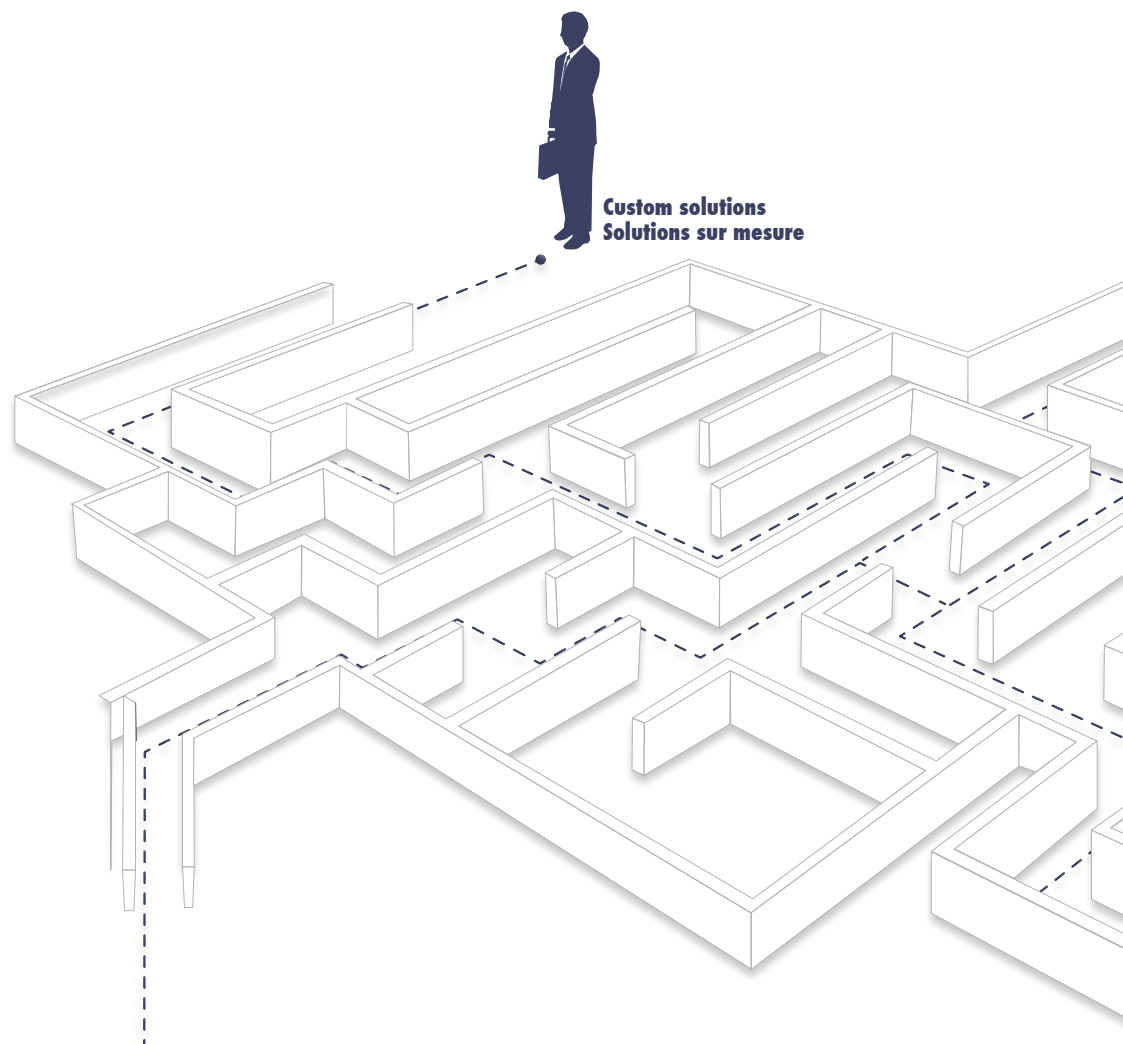


Supply chain

From long-term storage to preparation of specific commands with suitable packaging, from provision to your freight agent to delivery on site, Fazzini meets your requirements.

Chaîne logistique

Du stockage de longue durée à la préparation de commandes spécifiques avec packaging adapté, de la mise à disposition chez votre transitaire à la livraison sur site, Fazzini répond à vos exigences.



Procurement / project management

Fazzini offers its recognized expertise, appearing as single point of contact, managing all the benefits related to medical equipment (internal or third parties) to achieve the desired balance quality-cost-delivery.

Approvisionnement / gestion de projet

Fazzini met à disposition son expertise reconnue, en se présentant comme interlocuteur unique, réalisant l'intégralité des prestations liées aux équipements médicaux (internes ou tiers) afin d'atteindre l'équilibre qualité-coût-délai souhaité.



On-field services

Our team of experts and accredited partners offer local solutions tailored to your needs in the context of technical support.

- Installation
- Training
- After sales service
- Maintenance

Services locaux

Notre équipe d'experts et de partenaires accrédités proposent des solutions de proximité adaptées à vos besoins dans le cadre du support technique.

- Installation
- Formation
- Service après-vente
- Maintenance

QUALITY



1. Health is a right.
2. Everyone must have access to timely care acceptable, affordable and quality.
3. Facilities, health goods and services must be respectful of medical ethics. For these reasons Fazzini requires a suitable quality without compromise of its products that are individually checked before provision. Listening to customers, Fazzini teams have made the quality, more than a rule, an applied state of mind at every stage of the supply chain.

QUALITE

1. La santé est un droit.
2. Chacun doit pouvoir accéder en temps opportun à des soins acceptables, abordables et de qualité.
3. Installations, biens et services en matière de santé doivent être respectueux de l'éthique médicale. Pour ces raisons Fazzini exige une qualité adaptée et sans compromis de ses produits qui sont contrôlés individuellement avant mise à disposition. A l'écoute de ses clients, les équipes de Fazzini ont fait de la qualité, plus qu'une règle, un état d'esprit appliqué à chaque étape de la supply chain.

EC CERTIFICATE



ISO 13485



ISO 9001





Based on a strong local presence

Active on Italian national market and in 80 international countries representing 4 continents, Fazzini totalize more than 500 direct active customers each year.

Basés sur une forte empreinte locale

Active sur le marché national Italien et dans 80 pays à l'international représentant 4 continents, Fazzini compte chaque année plus de 500 clients actifs directs





PRIVATE SECTOR

A private sector through local and/or international accredited resellers.

SECTEUR PRIVE

Un secteur privé soutenu par des revendeurs locaux et/ou internationaux accrédités.



PUBLIC CLIENTS AND INSTITUTIONAL ORGANIZATIONS

CLIENTELE PUBLIQUE ET ORGANISMES INSTITUTIONNELS

**UNICEF - UNFPA - UNOPS - MEDECINS SANS FRONTIERES
- PSFCM - PSFA ETHIOPIA - PMU ERITREA**

and others/ et autres





A large product range

Covering 50 % of hospital needs in medical devices

Une large gamme de produits

50 % des besoins hospitaliers en dispositifs médicaux couverts

AVAILABILITY

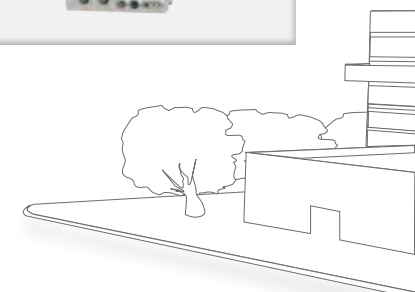
Because health cannot wait, a large majority of our products are available from stock to meet the most urgent needs.

DISPONIBILITE

Parce que la santé n'attend pas, une grande majorité de nos produits est disponible sur stock pour répondre aux besoins les plus urgents.



Surgical block / Bloc opératoire



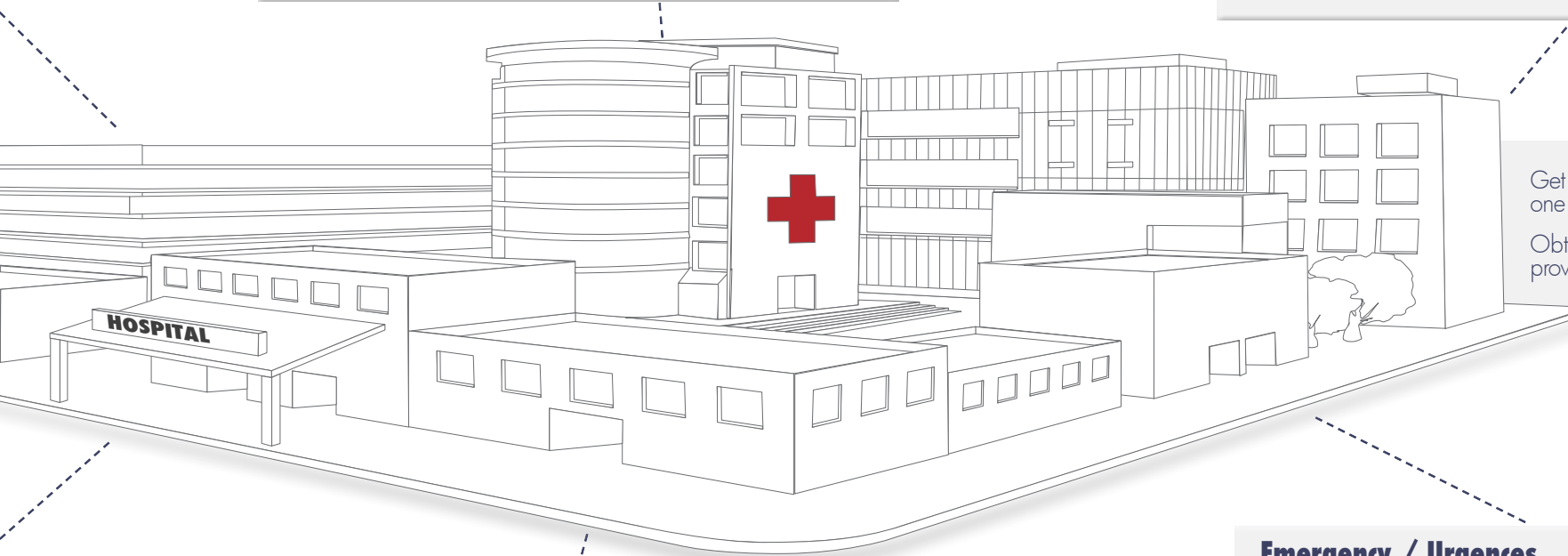
Maternity/ Maternité



Patient room / Chambre patient



Cardiology / Cardiologie



Get more than 3000 products from one source

Obtenez plus de 3000 produits provenant d'une source

Doctor's room / Cabinet médecin



Emergency / Urgences







Product Service

EC Certificate

Product Quality Assurance System

Directive 93/42/EEC on Medical Devices (MDD), Annex VI
(Devices in class IIa or IIb)

No. G3 16 06 44963 026

Manufacturer:**Fazzini s.r.l.**

SS Padana Sup. 317
20090 Vimodrone (MI)
ITALY

**Facility(ies):**

Fazzini s.r.l.
SS Padana Sup. 317, 20090 Vimodrone (MI), ITALY

**Product
Category(ies):****Suction Pumps**

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for final inspection and test of the respective devices / device categories in accordance with MDD Annex VI. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class IIb devices an additional Annex III certificate is mandatory. See also notes overleaf.

Report no.:

ITA274457

Valid from:

2016-10-22

Valid until:

2021-10-21

**Date,** 2016-09-30

Stefan Preiß

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

Page 1 of 1



Italia

CERTIFICATO

Nr. 50 100 5990/B - Rev.007

Si attesta che / This is to certify that

IL SISTEMA QUALITÀ DI
THE QUALITY SYSTEM OF

FAZZINI S.r.l.

SEDE LEGALE E OPERATIVA:
REGISTERED OFFICE AND OPERATIONAL SITE:

**STRADA STATALE PADANA SUPERIORE 317
IT - 20090 VIMODRONE (MI)**

È CONFORME AI REQUISITI DELLA NORMA
HAS BEEN FOUND TO COMPLY WITH THE REQUIREMENTS OF

UNI CEI EN ISO 13485:2016

SISTEMI QUALITÀ – DISPOSITIVI MEDICALI
QUALITY SYSTEMS – MEDICAL DEVICES

QUESTO CERTIFICATO È VALIDO PER IL SEGUENTE CAMPO DI APPLICAZIONE
THIS CERTIFICATE IS VALID FOR THE FOLLOWING SCOPE

**VEDI ALLEGATO 1
SEE ANNEX 1**



SGQ N° 049A

Membro degli Accordi di Mutuo Riconoscimento
EA, IAF e ILAC
Signatory of EA, IAF and ILAC Mutual
Recognition Agreements

Per l'Organismo di Certificazione
For the Certification Body
TÜV Italia S.r.l.

Validità / Validity
Dal / From: **2019-08-23**
Al / To: **2021-06-14**

Andrea Coscia
Direttore Divisione Business Assurance

Data emissione / Issuing Date
2019-08-23

PRIMA CERTIFICAZIONE / FIRST CERTIFICATION: 2006-07-02

"LA VALIDITÀ DEL PRESENTE CERTIFICATO È SUBORDINATA A SORVEGLIANZA PERIODICA A 12 MESI E AL RIESAME COMPLETO DEL SISTEMA DI GESTIONE AZIENDALE CON PERIODICITÀ TRIENNALE"

"THE VALIDITY OF THE PRESENT CERTIFICATE DEPENDS ON THE ANNUAL SURVEILLANCE EVERY 12 MONTHS AND ON THE COMPLETE REVIEW OF COMPANY'S MANAGEMENT SYSTEM AFTER THREE-YEARS"



■ SUCTION PUMP AND NEBULIZER

- Suction pump (F-18.00, F-36.00)
- Suction pump (F-20.00, F-40.00)
- Suction pump (F-30.00, F-35.00)
- Accessories suction pump
- Mobile surgical suction pump
- Suction pump AC/DC
- Foot operated suction pump (F-170)
- Pedal suction pump (F-175)
- Emergency suction pump (F-151)
- Vacuum extractor
- Aspiration canula
- Nebulizer

■ ASPIRATEUR ET NÉBULISEUR

- Aspirateur de mucosites (F-18.00, F-36.00)
- Aspirateur de mucosites (F-20.00, F-40.00)
- Aspirateur de mucosites (F-30.00, F-35.00)
- Accessoires aspirateur
- Pompe d'aspiration chirurgicale mobile
- Aspirateur de mucosites avec batterie
- Aspirateur manuel (F-170)
- Aspirateur manuel (F-175)
- Aspirateur manuel (F-151)
- Ventouse obstetricale
- Canule d'aspiration
- Nébuliseur



■ F-18.00

SUCTION PUMP

- Portable suction machine for minor surgery, posttracheotomy and home use. Anti-shock case, light, easy to carry and keep clean. Supplied with 1 lt. jar sterilizable, with overflow valve. Complete with suction regulator, vacuum gauge, disposable filter and set of tubes.
- Dimensions: 19 x 30 x 16cm

ASPIRATEUR DE MUCOSITES

- Aspirateur pour chirurgie mineure et posttrachéotomie. Idéal pour soins postopératoires à domicile. Boîtier en ABS antichoc, léger et facile à nettoyer. Livré avec bocal stérilisable de 1 litre et valve de reflux. Régulateur d'aspiration avec vacuomètre, filtre à usage unique et tubulure.
- Dimensions: 19 x 30 x 16cm

■ F-18/2.00

Suction pump with 2 liters jar /
Aspirateur de mucosites avec bocal de 2 litres

TECHNICAL SPECIFICATIONS / SPÉCIFICATIONS TECHNIQUES

Code / References	F-18.00
Motor / Moteur	Maintenance-free Oil free piston pump
Weight / Poids	2,4 kg
Power supply / Alimentation	230V/50-60Hz
Suction power / Débit	23 l/min
Max vacuum / Vide maximum	- 0,75 bar - 563 mmHg



■ F-36.00

SUCTION PUMP

- Portable suction machine for minor surgery, posttracheotomy and home use. Anti-shock case, light, easy to carry and keep clean. Supplied with 1 lt. jar sterilizable, with overflow valve. Complete with suction regulator, vacuum gauge, disposable filter and set of tubes.
- Dimensions: 19 x 30 x 16cm

ASPIRATEUR DE MUCOSITES

- Aspirateur pour chirurgie mineure et posttrachéotomie. Idéal pour soins postopératoires à domicile. Boîtier en ABS antichoc, léger et facile à nettoyer. Livré avec bocal stérilisable de 1 litre et valve de reflux. Régulateur d'aspiration avec vacuomètre, filtre à usage unique et tubulure.
- Dimensions: 19 x 30 x 16cm

■ F-36/2.00

Suction pump with 2 liters jar /
Aspirateur de mucosites avec bocal de 2 litres

TECHNICAL SPECIFICATIONS / SPÉCIFICATIONS TECHNIQUES

Code / References	F-36.00
Motor / Moteur	Maintenance-free Oil free piston pump
Weight / Poids	2,7 kg
Power supply / Alimentation	230V/50Hz 230V/60Hz
Suction power / Débit	30 l/min
Max vacuum / Vide maximum	- 0,80 bar - 600 mmHg



■ F-20.00

SUCTION PUMP

- Portable suction machine for minor surgery, post-surgery treatments, hospital use. Anti-shock case, light, easy to carry and keep clean. Supplied with 1 lt. jar sterilizable, with overflow valve. Complete with suction regulator, vacuum gauge, disposable filter and set of tubes.
- Dimensions: 22,5 x 37 x 25cm

ASPIRATEUR DE MUCOSITES

- Aspirateur pour chirurgie mineure, traitements post-opératoires et usage hospitalier avec puissant moteur à piston. Boîtier en ABS antichoc, léger et facile à nettoyer. Livré avec bocal stérilisable de 1 litre et valve de reflux. Régulateur d'aspiration avec vacuomètre, filtre à usage unique et jeu de tubulure.
- Dimensions: 22,5 x 37 x 25cm

■ F-20/2.00

Suction pump with 2 liters jar /
Aspirateur de mucosites avec bocal de 2 litres

TECHNICAL SPECIFICATIONS / SPÉCIFICATIONS TECHNIQUES

Code / References	F-20.00
Motor / Moteur	Maintenance-free Oil free piston pump
Weight / Poids	2,7 kg
Power supply / Alimentation	230V/50-60Hz
Suction power / Débit	25 l/min
Max vacuum / Vide maximum	- 0,75 bar - 563 mmHg



■ F-40.00

SUCTION PUMP

- Portable suction machine for minor surgery, post-surgery treatments, hospital use. Anti-shock case, light, easy to carry and keep clean. Supplied with 1 lt. jar sterilizable, with overflow valve. Complete with suction regulator, vacuum gauge, disposable filter and set of tubes.
- Dimensions: 22,5 x 37 x 25cm

ASPIRATEUR DE MUCOSITES

- Aspirateur pour chirurgie mineure, traitements post-opératoires et usage hospitalier avec puissant moteur à piston. Boîtier en ABS antichoc, léger et facile à nettoyer. Livré avec bocal stérilisable de 1 litre et valve de reflux. Régulateur d'aspiration avec vacuomètre, filtre à usage unique et jeu de tubulure.
- Dimensions: 22,5 x 37 x 25cm

■ F-40/2.00

Suction pump with 2 liters jar /
Aspirateur de mucosites avec bocal de 2 litres

TECHNICAL SPECIFICATIONS / SPÉCIFICATIONS TECHNIQUES

Code / References	F-40.00
Motor / Moteur	Maintenance-free Oil free piston pump
Weight / Poids	2,9 kg
Power supply / Alimentation	230V/50-60Hz
Suction power / Débit	32 l/min
Max vacuum / Vide maximum	- 0,80 bar - 600 mmHg



■ F-30.00

SUCTION PUMP

- Portable suction machine for professional use and surgery treatment, with powerful piston motor. ABS anti-shock case, easy to carry and keep clean. Supplied with 1 lt. jar autoclavable with overflow valve. Suction regulator, vacuum gauge, disposable filter and set of tubes.
- Dimensions: 45 x 15 x 28cm

ASPIRATEUR DE MUCOSITES

- Aspirateur pour chirurgie mineure avec puissant moteur à piston. Idéal pour soins post-opératoires à domicile. Boîtier en ABS antichoc. Livré avec bocal stérilisable de 1 litre et valve de reflux. Régulateur d'aspiration avec vacuomètre. Filtre à usage unique et jeu de tubulure.
- Dimensions: 45 x 15 x 28cm

REFERENCES

- F-30.00 1 x 1 lt.
- F-30.20 1 x 2 lt.
- F-30.40 2 x 1 lt.
- F-30.60 2 x 2 lt.

TECHNICAL SPECIFICATIONS / SPÉCIFICATIONS TECHNIQUES

Code / References	F-30.00
Motor / Moteur	Maintenance-free Oil free piston pump
Weight / Poids	4,8 kg
Power supply / Alimentation	230V/50-60Hz
Suction power / Débit	40 l/min
Max vacuum / Vide maximum	-0,80 bar -600 mmHg



■ F-35.00

SUCTION PUMP

- Portable suction machine for professional use and surgery treatment, with powerful piston motor. ABS anti-shock case, easy to carry and keep clean. Supplied with 1 lt. jar autoclavable with overflow valve. Suction regulator, vacuum gauge, disposable filter and set of tubes.
- Dimensions: 45 x 15 x 28cm

ASPIRATEUR DE MUCOSITES

- Aspirateur pour chirurgie mineure avec puissant moteur à piston. Idéal pour soins post-opératoires à domicile. Boîtier en ABS antichoc. Livré avec bocal stérilisable de 1 litre et valve de reflux. Régulateur d'aspiration avec vacuomètre. Filtre à usage unique et jeu de tubulure.
- Dimensions: 45 x 15 x 28cm

REFERENCES

- F-35.00 1 x 1 lt.
- F-35.20 1 x 2 lt.
- F-35.40 2 x 1 lt.
- F-35.60 2 x 2 lt.

TECHNICAL SPECIFICATIONS / SPÉCIFICATIONS TECHNIQUES

Code / References	F-35.00
Motor / Moteur	Maintenance-free Oil free piston pump
Weight / Poids	5,3 kg
Power supply / Alimentation	230V/50-60Hz
Suction power / Débit	50 l/min
Max vacuum / Vide maximum	-0,80 bar -600 mmHg



F-33.01

TROLLEY FOR SUCTION PUMP

- Epoxy painted steel trolley mounted on 4 castors, two of which with brakes.
- Trolley suitable for suction pumps series F-30.00 / F-31.00 / F-35.00

CHARIOT POUR ASPIRATEUR

- Chariot en acier avec 4 roulettes, dont 2 avec freins.
- Chariot compatible avec aspirateurs F-30.00 / F-31.00 / F-35.00



05.0017

FOOTSWITCH FOR SUCTION PUMP

- Vacuum gauge regulation.

PEDALE POUR ASPIRATEUR

- Régulation du vide.

- SUITABLE FOR / UTILISABLE AVEC
F-30.XX/P
F-31.XX/P
F-35.XX/P
FX50 Series / Série
F-60 Series / Série
F-90 Series / Série
F-100 Series / Série



MEDIFLOW BAG

- **MO43001** Non-sterile bag 1 Lt / Sac non stérile 1 Lt
- **MO45002** Non-sterile bag 2 Lt / Sac non stérile 2 Lt
- Non-sterile bag for collecting body fluids in surgery disposable. Medical latex free polyethylene. Minimum pressure -560 mmHg (-750 mbar). Avoid contact with the aspirated secretions.

MEDIFLOW BAG

- Sac non stérile de collecte des liquides corporels en chirurgie, à usage unique. Polyéthylène médical sans latex. Pression minimale -560 mmHg (-750 mbar). Evite tout contact avec les sécrétions aspirées.



05.0016

ANTIBACTERIAL AND ANTIVIRAL FILTER

- Disposable.

FILTRE ANTIBACTÉRIEN ET ANTIVIRAL

- Jetable.



- AUTOCLAVABLE 121°
05.0001 1 L
05.0002 2 L
05.0004 4 L
- SINGLE USE/
USAGE UNIQUE
D11T 1 L
D21T 2 L
D41T 4 L

JARS

- Autoclavable jars for suction pumps made of polycarbonate (Makrolon) autoclavable at 121°C. Silkscreened graduated scale resistant to aggressive liquids and disinfectants.

BOCAUX

- Bocaux pour aspirateurs. Polycarbonate (Makrolon) autoclavable à 121°C. Graduation résistante aux liquides agressifs et désinfectants.



ASPIRATION CANULA

- Aspiration canula, made of stainless steel.

CANULE D'ASPIRATION

- En acier inoxydable.

05.25006 ø 6 mm
05.25008 ø 8 mm
05.25010 ø 10 mm
05.25012 ø 12 mm
05.25014 ø 14 mm

OPTIONAL
05.25015
Connector / Adaptateur



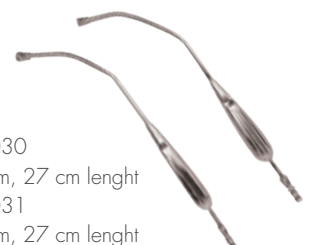
05.25000

UTERINE ASPIRATION CANULA

- Made of stainless steel with handle for suction regulation. Canula ø 6/8/10/12/14 mm

CANULES INTRA-UTÉRINES

- Set comprenant 5 canules en acier inoxydable avec manche régulateur d'aspiration
Canules ø 6/8/10/12/14 mm



05.7030
ø 6 mm, 27 cm lenght
05.7031
ø 8 mm, 27 cm lenght

ASPIRATION CANULA

- Yankauer aspiration canula with handle, made of stainless steel 27cm lenght.

CANULE D'ASPIRATION

- Canule avec manche de Yankauer, en acier inoxydable. Longueur 27 cm.



■ F-60

SURGICAL SUCTION PUMP

- Mobile suction unit for professional use with double piston motor.
- ABS anti-shock case with four castors two of which with brakes.
- Vacuum gauge and vacuum regulator.
- Standard configuration with two jars of 2 lt made of autoclavable makrolon with double security valve.
- Supplied with disposable filter, set of tubes and foot switch predisposition.
- Dimensions: 48 x 46 x 42cm

POMPE D'ASPIRATION CHIRURGICALE

- Unité d'aspiration mobile à usage professionnel avec moteur à double piston. Boîtier ABS anti-choc avec quatre roulettes dont deux avec freins. Vacuometre et régulateur de vide. Configuration standard avec deux bouches de 2 lt en makrolon autoclavable avec double soupape de sécurité.
- Fourni avec filtre jetable, jeu de tubes et prédisposition pour la pédale commutateur.
- Dimensions: 48 x 46 x 42cm

AVAILABLE CONFIGURATIONS / CONFIGURATIONS DISPONIBLES

- F-60/F 2 x 2 lt. Footswitch / commande au pied
 F-60/4 2 x 4 lt.
 F-60/F4 2 x 4 lt. Footswitch / commande au pied

TECHNICAL SPECIFICATIONS / SPÉCIFICATIONS TECHNIQUES

Code / References	F-60
Motor / Moteur	Maintenance-free Oil free piston pump
Weight / Poids	11 kg
Power supply / Alimentation	230V/50-60Hz
Suction power / Débit	70 l/min
Max vacuum / Vide maximum	- 0,80 bar - 600 mmHg

■ F-90

SURGICAL SUCTION PUMP

- Mobile suction unit for professional use with double piston motor.
- ABS anti-shock case with four castors two of which with brakes.
- Vacuum gauge and vacuum regulator.
- Standard configuration with two jars of 2 lt made of autoclavable makrolon with double security valve.
- Supplied with disposable filter, set of tubes and foot switch predisposition.
- Dimensions: 48 x 46 x 42cm

POMPE D'ASPIRATION CHIRURGICALE

- Unité d'aspiration mobile à usage professionnel avec moteur à double piston. Boîtier ABS anti-choc avec quatre roulettes dont deux avec freins. Vacuometre et régulateur de vide. Configuration standard avec deux bouches de 2 lt en makrolon autoclavable avec double soupape de sécurité.
- Fourni avec filtre jetable, jeu de tubes et prédisposition pour la pédale commutateur.
- Dimensions: 48 x 46 x 42cm

AVAILABLE CONFIGURATIONS / CONFIGURATIONS DISPONIBLES

- F-90/F 2 x 2 lt. Footswitch / commande au pied
 F-90/4 2 x 4 lt.
 F-90/F4 2 x 4 lt. Footswitch / commande au pied

TECHNICAL SPECIFICATIONS / SPÉCIFICATIONS TECHNIQUES

Code / References	F-90
Motor / Moteur	Maintenance-free Oil free piston pump
Weight / Poids	13 kg
Power supply / Alimentation	230V/50-60Hz
Suction power / Débit	90 l/min
Max vacuum / Vide maximum	- 0,80 bar - 600 mmHg





- Efficient aluminum motor double piston



■ F-X50

HIGH VACUUM SUCTION PUMP

- Mobile suction unit with double piston aluminium motor. ABS anti-shock case with four castors two of which with brakes. Vacuum gauge and vacuum regulator. aluminum engine, with it's unique transmission system and vertical piston, is super quiet and designed for intensive and continuous use in particular environments where quietness and efficiency are needed. Standard configuration with two jars of 2 Lt made of autoclavable makrolon.
- Dimensions: 48 x 46 x 42cm

POMPE D'ASPIRATION À VIDE POUSSÉ

- Unité d'aspiration mobile avec moteur en aluminium à double piston. Boîtier ABS anti-choc avec quatre roulettes dont deux avec freins. Vacuometre et régulateur de vide. Le moteur en aluminium est doté d'un système de transmission unique et d'un piston vertical, extrêmement silencieux et conçu pour une utilisation intensive et continue dans des environnements particuliers où silence et efficacité sont nécessaires. Avec deux boccas de 2 Lt en makrolon autoclavable
- Dimensions: 48 x 46 x 42cm

AVAILABLE CONFIGURATIONS / CONFIGURATIONS DISPONIBLES

FX50/F 2 x 2 Lt. Footswitch / commande au pied

FX50/4 2 x 4 Lt.

FX50/F4 2 x 4 Lt. Footswitch / commande au pied

TECHNICAL SPECIFICATIONS / SPÉCIFICATIONS TECHNIQUES

Code / References	F-X50
Motor / Moteur	Maintenance-free Oil free piston pump
Weight / Poids	17 kg
Power supply / Alimentation	230V/50Hz
Suction power / Débit	35 l/min
Max vacuum / Vide maximum	- 0,90 bar - 675 mmHg

■ F-100

HIGH VACUUM SUCTION PUMP

- Mobile suction unit for professional use with double piston metal motor. ABS anti-shock case with four castors two of which with brakes.
- Vacuum gauge and vacuum regulator.
- F-100 metal engine is very quiet and designed for intensive use
- Standard configuration with two jars of 2 Lt made of autoclavable makrolon with double security valve.
- Dimensions: 48 x 46 x 42cm

POMPE D'ASPIRATION À VIDE POUSSÉ

- Unité d'aspiration mobile à usage professionnel avec moteur en acier à double piston. Boîtier ABS anti-choc avec quatre roulettes dont deux avec freins. Vacuometre et régulateur de vide. Configuration standard avec deux boccas de 2 Lt en makrolon autoclavable avec double soupape de sécurité
- Fourni avec filtre jetable, jeu de tubes et prédisposition pour la pédale commutateur.
- Dimensions: 48 x 46 x 42cm

AVAILABLE CONFIGURATIONS / CONFIGURATIONS DISPONIBLES

F-100/F 2 x 2 Lt. Footswitch / commande au pied

F-100/4 2 x 4 Lt.

F-100/F4 2 x 4 Lt. Footswitch / commande au pied

TECHNICAL SPECIFICATIONS / SPÉCIFICATIONS TECHNIQUES

Code / References	F-100
Motor / Moteur	Maintenance-free Oil free piston pump
Weight / Poids	18 kg
Power supply / Alimentation	230V/50-60Hz
Suction power / Débit	80 l/min
Max vacuum / Vide maximum	- 0,90 bar - 675 mmHg





DIGITAL DISPLAY

- Same features of the corresponding model BUT with digital display (gauge)
- Dimensions: 48 x 46 x 42cm

AFFICHAGE DIGITAL

- Caractéristiques identiques au modèle correspondant MAIS avec indicateur numérique
- Dimensions: 48 x 46 x 42cm

AVAILABLE CONFIGURATIONS / CONFIGURATIONS DISPONIBLES

F-60D	2 x 2 lt.	F-X50D	2 x 2 lt.
F-60D/F	2 x 2 lt. Footswitch/ commande au pied	F-X50D/F	2 x 2 lt. Footswitch/ commande au pied
F-60D/4	2 x 4 lt.	F-X50D/4	2 x 4 lt.
F-60D/F4	2 x 4 lt. Footswitch/ commande au pied	F-X50D/F4	2 x 4 lt. Footswitch/ commande au pied
F-90D	2 x 2 lt.	F-100D	2 x 2 lt.
F-90D/F	2 x 2 lt. Footswitch/ commande au pied	F-100D/F	2 x 2 lt. Footswitch/ commande au pied
F-90D/4	2 x 4 lt.	F-100D/4	2 x 4 lt.
F-90D/F4	2 x 4 lt. Footswitch/ commande au pied	F-100D/F4	2 x 4 lt. Footswitch/ commande au pied



CHANGEOVER VALVE

- Same features of the corresponding model BUT with manual changeover valve
- Dimensions: 48 x 46 x 42cm

VANNE D'INVERSION

- Caractéristiques identiques au modèle correspondant MAIS avec vanne d'inversion manuelle
- Dimensions: 48 x 46 x 42cm

AVAILABLE CONFIGURATIONS / CONFIGURATIONS DISPONIBLES

F-60R	2 x 2 lt.	F-X50R	2 x 2 lt.
F-60R/F	2 x 2 lt. Footswitch/ commande au pied	F-X50R/F	2 x 2 lt. Footswitch/ commande au pied
F-60R/4	2 x 4 lt.	F-X50R/4	2 x 4 lt.
F-60R/F4	2 x 4 lt. Footswitch/ commande au pied	F-X50R/F4	2 x 4 lt. Footswitch/ commande au pied
F-90R	2 x 2 lt.	F-100R	2 x 2 lt.
F-90R/F	2 x 2 lt. Footswitch/ commande au pied	F-100R/F	2 x 2 lt. Footswitch/ commande au pied
F-90R/4	2 x 4 lt.	F-100R/4	2 x 4 lt.
F-90R/F4	2 x 4 lt. Footswitch/ commande au pied	F-100R/F4	2 x 4 lt. Footswitch/ commande au pied





■ COMPARISON DATA SHEET SUCTION PUMP / TABLEAU DE COMPARAISON ASPIRATEUR

MODEL	F-18.00	F-20.00	F-30.00	F-35.00	F-36.00	F-40.00
CE MARK	YES	YES	YES	YES	YES	YES
CONFIGURATION	PORTABLE	PORTABLE	PORTABLE	PORTABLE	PORTABLE	PORTABLE
PUMP TYPE	PISTON	PISTON	PISTON	PISTON	PISTON	PISTON
Number of pumps	1	1	1	1	1	1
VACUUM LIMIT, mm Hg	- 563 mm Hg	- 563 mm Hg	-600 mm Hg	-600 mm Hg	- 600 mm Hg	- 600 mm Hg
Free airflow, L/min	23 L/min	25 L/min	40 L/min	50 L/min	30 L/min	32 L/min
Gauge diam, cm (in)	1.07 (0.42)	0.89 (0.35)	0.92 (0.36)	0.92 (0.36)	1.07 (0.42)	0.89 (0.35)
Material	MAKROLON AUTOCLAVABLE	MAKROLON AUTOCLAVABLE	MAKROLON AUTOCLAVABLE	MAKROLON AUTOCLAVABLE	MAKROLON AUTOCLAVABLE	MAKROLON AUTOCLAVABLE
Number	1	1	1	1	1	1
Capacity limit line, mL	1.000	1.000	1.000	1.000	1.000	1.000
Overflow protection	YES	YES	YES	YES	YES	YES
Reusable/disposable	DISPOSABLE	DISPOSABLE	DISPOSABLE	DISPOSABLE	DISPOSABLE	DISPOSABLE
FILTER TYPE	Bacterial, hydrophobic	Bacterial, hydrophobic	Bacterial, hydrophobic	Bacterial, hydrophobic	Bacterial, hydrophobic	Bacterial, hydrophobic
VAC	110/230	110/230	110/230	110/230	110/230	110/230
W or VA	121VA	121VA	55VA	60VA	121VA	121VA
H x W x D, cm	30X19X16	37X22.5X25	45X15X28	45X15X28	30X19X16	37X22.5X25
WEIGHT, kg	2,4	2,7	4,8	5,3	2,7	2,9
APPLICATIONS	Minor surgery, ENT, Home use	Minor surgery, ENT, Home use	Minor surgery, ENT	Surgery treatment	Minor surgery, ENT, Home use	Minor surgery, ENT, Home use

■ COMPARISON DATA SHEET SUCTION PUMP / TABLEAU DE COMPARAISON ASPIRATEUR

MODEL	F-60	F-90	F-100	F-X50
CE MARK	YES	YES	YES	YES
CONFIGURATION	MOBILE	MOBILE	MOBILE	MOBILE
PUMP TYPE	PISTON	PISTON	PISTON	PISTON
Number of pumps	2	2	2	2
VACUUM LIMIT, mm Hg	-600 mm Hg	-600 mm Hg	-675 mm Hg	-675 mm Hg
Free airflow, L/min	70 L/min	90 L/min	80 L/min	35 L/min
Gauge diam, cm (in)	1.07 (0.42)	1.07 (0.42)	1.07 (0.42)	1.07 (0.42)
Material	MAKROLON AUTOCLAVABLE	MAKROLON AUTOCLAVABLE	MAKROLON AUTOCLAVABLE	MAKROLON AUTOCLAVABLE
Number	2	2	2	2
Capacity limit line, mL	2.000	2.000	2.000	2.000
Overflow protection	YES	YES	YES	YES
Reusable/disposable	DISPOSABLE	DISPOSABLE	DISPOSABLE	DISPOSABLE
FILTER TYPE	Bacterial, hydrophobic	Bacterial, hydrophobic	Bacterial, hydrophobic	Bacterial, hydrophobic
VAC	110/230	110/230	110/230	230
W or VA	60W	200W	270W	200W
H x W x D, cm	48X46X42	48X46X42	48X46X42	48X46X42
WEIGHT, kg	11	13	18	17
APPLICATIONS	Surgery treatment	Surgery treatment	Surgery tre- atment	Surgery tre- atment



■ F-18 BATTERY

SUCTION PUMP AC/DC

- Portable suction machine for minor surgery, emergency, patient transfer, hospital and home use. Anti-shock case, light, easy to carry and keep clean. Supplied with 1 lt. jar sterilizable, with overflow valve. Complete with suction regulator, vacuum gauge and rechargeable battery (Lead 12V - 1,3 Ah).
- Dimensions: 19 x 30 x 16cm

ASPIRATEUR DE MUCOSITES AVEC BATTERIE

- Aspirateur pour chirurgie mineure, d'urgence, transfert des patients, usage hospitalier et domestique. Boîtier en ABS anti-chocs, livré avec un bocal de 1 lt. stérilisable et valve de reflux. Complet avec régulateur d'aspiration avec vacuomètre et une batterie rechargeable (plomb 12V - 1,3 Ah).
- Dimensions: 19 x 30 x 16cm

AVAILABLE CONFIGURATIONS / CONFIGURATIONS DISPONIBLES

F-18 BATTERY	1 x 1 L
F-18B/2.00	1 x 2 L

TECHNICAL SPECIFICATIONS / SPÉCIFICATIONS TECHNIQUES

Code / References	F-18 BATTERY
Motor / Moteur	Maintenance-free Oil free piston pump
Weight / Poids	3,1 kg
Power supply / Alimentation	230V/ 50-60Hz AC/12V CC
Suction power / Débit	24 l/min
Max vacuum / Vide maximum	- 0,75 bar - 560 mmHg
Battery duration / Autonomie de la batterie	> 40 min



■ F-31.00

SUCTION PUMP AC/DC WITH LITHIUM BATTERY

- The NEW F-31 is a portable suction machine for minor surgery, emergency and professional use, with NEW powerful piston motor. ABS anti-shock case, light, easy to carry and keep clean. Supplied with 1 lt. jar sterilizable, with overflow valve. Complete with suction regulator, vacuum gauge. Filter disposable, set of disposable tubes and car plug connector. LIGHT WEIGHT
- Dimensions: 45 x 15 x 28cm

ASPIRATEUR DE MUCOSITES AVEC BATTERIE AU LITHIUM

- Aspirateur pour chirurgie mineure et premier secours avec nouveau puissant moteur à piston. Boîtier en ABS antichoc, léger et facile à nettoyer. Livré avec bocal stérilisable de 1 litre et valve de reflux. Régulateur d'aspiration avec vacuomètre. Filtre à usage unique. Jeu de tubulure à usage unique. Adaptateur pour prise allume-cigare.
- Dimensions: 45 x 15 x 28cm

AVAILABLE CONFIGURATIONS / CONFIGURATIONS DISPONIBLES

F-31.00	1 x 1 L	F-31.20	1 x 2 L
F-31.40	2 x 1 L	F-31.60	2 x 2 L

TECHNICAL SPECIFICATIONS / SPÉCIFICATIONS TECHNIQUES

Code / References	F-31.00
Motor / Moteur	Maintenance-free Oil free piston pump
Weight / Poids	3,2 kg
Power supply / Alimentation	240 -100 50/60Hz 15Vcc (4A)
Suction power / Débit	40 l/min
Max vacuum / Vide maximum	- 0,80 bar - 560 mmHg
Battery duration / Autonomie de la batterie	> 105 min



F-60B

HIGH VACUUM SUCTION PUMP AC/DC

- Mobile suction machine for professional use, with powerful double piston motor. ABS anti-shock case. Four antistatic castors, two of which with brakes. Vacuum gauge for the control of vacuum. Vacuum regulation. Two jars, 2 lt. capacity made of Makrolon autoclavable. Each jar with double security valve. Independent use of each jar. Supplied with disposable filter and set of tubes.
- Dimensions: 48 x 46 x 42cm

POMPE D'ASPIRATION À VIDE POUSSÉ AC/DC

- Aspirateur mobile avec puissant moteur à double piston. Boîtier en ABS antichoc avec quatre roulettes antistatiques, dont 2 avec freins. Livré avec 2 bouchons Makrolon autoclavables de 2 litres indépendants et double valve de reflux. Régulateur de dépression avec vacuomètre. Fourni avec filtre jetable et un jeu de tubes
- Dimensions: 48 x 46 x 42cm

AVAILABLE CONFIGURATIONS / CONFIGURATIONS DISPONIBLES

- F-60B 2 x 2 lt.
- F-60B/F 2 x 2 lt. footswitch / pédale
- F-60B/4 2 x 4 lt.
- F-60B/F4 2 x 4 lt. footswitch / pédale

TECHNICAL SPECIFICATIONS / SPÉCIFICATIONS TECHNIQUES

Code / References	F-60B
Motor / Moteur	Maintenance-free Oil free piston pump
Weight / Poids	9,9 kg
Power supply / Alimentation	230V/50-60Hz
Suction power / Débit	55 l/min
Max vacuum /	
Vide maximum	- 0,80 bar - 600 mmHg
Battery duration /	
Autonomie de la batterie	> 60 min



COMPARISON DATA SHEET SUCTION PUMP / TABLEAU DE COMPARAISON ASPIRATEUR

MODEL	F-18 BATTERY	F-31.00	F-60B
CE MARK	YES	YES	YES
CONFIGURATION	PORTABLE	PORTABLE	MOBILE
PUMP TYPE	PISTON	PISTON	PISTON
Number of pumps	1	1	2
VACUUM LIMIT, mm Hg	-560 mm Hg	-560 mm Hg	-600 mm Hg
Free airflow, L/min	24 L/min	40 L/min	55 L/min
Gauge diam, cm (in)	1.07 (0.42)	0.92 (0.36)	1.07 (0.42)
Material	MAKROLON AUTOCLAVABLE	MAKROLON AUTOCLAVABLE	MAKROLON AUTOCLAVABLE
Number	1	1	2
Capacity limit line, mL	1.000	1.000	2.000
Overflow protection	YES	YES	YES
Reusable/disposable	DISPOSABLE	DISPOSABLE	DISPOSABLE
FILTER TYPE	Bacterial, hydrophobic	Bacterial, hydrophobic	Bacterial, hydrophobic
Power consumption	230V AC / 19W	240 - 100, 50/60Hz	230V AC/12Vcc
Puissance absorbée	12 Vcc 5W	15 Vcc 4A	40V 12W - 230V 240W
H x W x D, cm	30x19x16	45x15x28	48x46x42
WEIGHT, kg	3,1	3,2	9,9
APPLICATIONS	Minor surgery, Emergency	Emergency, Minor surgery	Surgery treatment



F-170

FOOT OPERATED SUCTION PUMP

- Foot operated suction pump. Membrane emergency suction pump, foot or hand operated with ABS anti shock case
- Supplied with 1 lt autoclavable jar, disposable filter and set of tubes
- Dimensions: 26 x 18 x 24cm

ASPIRATEUR DE MUCOSITES MANUEL

- Aspirateur de mucosites manuel. Pompe d'aspiration d'urgence à membrane, fonctionnement à pédale ou à la main, boîtier anti-choc en ABS
- Fourni avec un bocal autoclavable de 1 litre, un filtre jetable et un jeu de tubes
- Dimensions: 26 x 18 x 24cm

TECHNICAL SPECIFICATIONS / SPÉCIFICATIONS TECHNIQUES

Code / References	F-170
Weight / Poids	1,6 kg
Suction power / Débit	10 l/min
Max vacuum / Vide maximum	- 0,45 bar - 190 mmHg

F-170/B

ELECTRIC FOOT ASPIRATION PUMP

- Emergency electrical and manual operated suction pump. This innovative emergency suction pump can be operated manually or electrically with ABS anti shock case is supplied with 1 lt autoclavable jar, disposable filter and set of tubes
- Dimensions: 26 x 18 x 24cm

ASPIRATEUR A PEDALE ÉLECTRIQUE

- Aspirateur a pedale électrique. Cette pompe d'aspiration d'urgence innovante peut être actionnée manuellement ou électriquement En ABS anti-choc, est fourni avec un bocal autoclavable de 1 litre, un filtre jetable et un jeu de tubes
- Dimensions: 26 x 18 x 24cm

TECHNICAL SPECIFICATIONS / SPÉCIFICATIONS TECHNIQUES

Code / References	F-170B
Weight / Poids	2 kg
Suction power / Débit	14 l/min
Max vacuum / Vide maximum	- 0,69 bar - 518 mmHg
Noisiness / Niveau sonore	52 dB





■ F-175

HIGH FLOW PEDAL SUCTION UNIT

- Powerful piston machine with single-way valve for instant vacuum and high flow
- Sturdy metallic construction
- Supplied with autoclavable 1 lt jar, disposable filter and set of tubes.
- Dimensions: 32 x 23 x 28 cm

ASPIRATEUR DE MUCOSITE MANUEL

- Machine à piston puissante, avec soupape à une voie pour un vide instantané et un débit élevé
- Construction métallique robuste
- Fourni avec un bocal autoclavable de 1 litre, un filtre jetable et un jeu de tubes.
- Dimensions: 32 x 23 x 28 cm

TECHNICAL SPECIFICATIONS / SPECIFICATIONS TECHNIQUES

Code / References	F-175
Weight / Poids	4 kg
Suction power / Débit	≥70 l/min
Max vacuum / Vide maximum	-0,90 bar - 675 mmHg



■ F-175/2

HIGH FLOW PEDAL SUCTION UNIT

- Supplied with 2 autoclavable 1 lt jars, disposable filter and set of tubes
- Dimensions: 32 x 23 x 28 cm

ASPIRATEUR DE MUCOSITE MANUEL

- Fourni avec 2 bocaux autoclavables de 1 litre, un filtre jetable et un jeu de tubes
- Dimensions: 32 x 23 x 28 cm



■ F-151

EMERGENCY MANUAL SUCTION PUMP

- Functional, safe, portable, powerful and economic suction pump, it works by means of the pressure given by one hand. In emergency situations it allows the suction of the airways secretions with safety, quickness and efficacy.
- Dimensions: 12,5 x 6 x 16 cm

TECHNICAL SPECIFICATIONS / SPECIFICATIONS TECHNIQUES

Code / References	F-151
Weight / Poids	192 g
Suction power / Débit	≥20 l/min
Max vacuum / Vide maximum	-0,25 bar

STANDARD ACCESSORIES / ACCESSOIRES STANDARD

- F-151.01 Spare jar for/ Bocal de recharge
- F-151.02 Set of 2 catheters (adult and child) / Jeu de 2 cathéters (adulte et enfant)

ASPIRATEUR DE MUCOSITES MANUEL

- Aspirateur de sécrétions fonctionnel, sûr, portable, puissant et économique. Il fonctionne par pompe à main sans nécessité de source électrique. Son petit format permet de l'inclure dans tous sac d'urgence ou ambulance.
- Dimensions: 12,5 x 6 x 16 cm



■ 05.09993 KIT 1

HAND-OPERATED VACUUM DEVICE

- Manual vacuum pump in chromed steel.
- 2 Silicone tubing.
- 1 liter jar autoclavable with vacuum gauge.
- 3 Suction cup ø 40 / 50 / 60 mm
- Stainless steel supporting basket

VENTOUSE OBSTETRICALE MANUELLE

- Pompe à vide manuelle en acier chromé.
- 2 Tubulure de silicone.
- Bocal 1 litre autoclavable avec vacuomètre.
- 3 Ventouse ø 40 / 50 / 60 mm
- Panier de support en acier inox

■ 05.09993 KIT 2

HAND-OPERATED VACUUM DEVICE

- Manual vacuum pump in chromed steel.
- 2 Silicone tubing.
- 1 liter jar autoclavable with vacuum gauge.
- Anterior suction cup
- Traction handle, made in stainless steel
- Stainless steel supporting basket

VENTOUSE OBSTETRICALE MANUELLE

- Pompe à vide manuelle en acier chromé.
- 2 Tubulure de silicone.
- Bocal 1 litre autoclavable avec vacuomètre.
- 3 Ventouse antérieure
- Poignée de traction, en acier inoxydable.
- Panier de support en acier inox

■ 05.09993 KIT 3

HAND-OPERATED VACUUM DEVICE

- Manual vacuum pump in chromed steel.
- 3 Silicone tubing.
- 1 liter jar autoclavable with vacuum gauge.
- Anterior suction cup ø 40 / 50 / 60 mm
- Posterior Cup ø 40 / 50 / 60 mm
- Traction handle, made in stainless steel
- Stainless steel supporting basket

VENTOUSE OBSTETRICALE MANUELLE

- Pompe à vide manuelle en acier chromé.
- 3 Tubulure de silicone.
- Bocal 1 litre autoclavable avec vacuomètre.
- 3 Ventouse antérieure ø 40 / 50 / 60 mm
- 3 Ventouse postérieure ø 40 / 50 / 60 mm
- Poignée de traction, en acier inoxydable.
- Panier de support en acier inox



■ SUCTION CUP

- Suction cup, made of stainless steel, complete with handle.

■ VENTOUSES

- Coupe de succion, en acier inoxydable, avec poignée.

05.10004 ø 40 mm
05.10005 ø 50 mm
05.10006 ø 60 mm
05.10007
Set of 3 sizes / tailles,
40/50/60 mm



■ SILICONE VACUUM CUP

- Available in three sizes. Made of medical grade silicone rubber. Polysulfone handle for light weight. Autoclavable 134°.

05.6000 ø 50 mm
05.6001 ø 60 mm
05.6002 ø 70 mm

■ VENTOUSE EN SILICONE

- Contact plus doux que l'inox. Légère et lisse elle peut être manipulée aisément. Poignée en polysulfone. Autoclavable à 134°.



■ ANTERIOR SUCTION CUP

- Anterior suction cup, made of stainless steel.

■ VENTOUSE ANTÉRIEURE

- Pour position occipito-antérieure. En acier inoxydable.

05.20404 ø 40 mm
05.20405 ø 50 mm
05.20406 ø 60 mm

OPTIONAL
05.30700
Traction handle, made in
stainless steel /
Poignée de traction, en
acier inoxydable.



■ POSTERIOR SUCTION CUP

- made of stainless steel.

05.20407 ø 40 mm
05.20408 ø 50 mm
05.20409 ø 60 mm

■ VENTOUSE POSTÉRIEURE

- En acier inoxydable.



■ 05.09993

HAND-OPERATED VACUUM DEVICE

- Manual vacuum pump in chromed steel. Silicone tubing. 1 liter jar autoclavable with vacuum gauge.

VENTOUSE OBSTETRICALE MANUELLE

- Pompe à vide manuelle en acier chromé. Tubulure de silicone. Bocal 1 litre autoclavable avec vacuomètre



■ REA0720.01

CARRYING CASE

- ABS case with fixing support
- Dim: 40 x 26 x 13 H (cm).

MALETTE DE RANGEMENT

- Mallette de réanimation en ABS
- Dim: 40 x 26 x 13 H (cm).



■ F-210 PRO

HEAVY DUTY PROFESSIONAL NEBULIZER

- Professional Aerosol Compressor for continuous use
- Adjustable flow regulation by an easy-to-turn knob, guaranteeing accurate delivery to patients.
- Ergonomically designed for easy use and transportation can be mounted on a movable trolley
- Dimensions: 32 x 15 x 28cm

NEBULISEUR PROFESSIONNEL

- Aérosol Professionnel à usage continu
- Réglage du flux au moyen d'une poignée tournant facilement, pour garantir une bonne distribution aux patients.
- Design ergonomique pour en faciliter l'utilisation et le transport. Peut être monté sur un chariot
- Dimensions: 32 x 15 x 28cm

TECHNICAL SPECIFICATIONS / SPÉCIFICATIONS TECHNIQUES

Weight / Poids	2,2 kg
Power supply / Alimentation	230V/50/60 Hz
Nebulization flow / Flux de nébulisation	32 L/min
Nebulization / Nébulisation	2cc/7-8min
Max pump pressure / Pression max del la pompe	3,4 bar

STANDARD ACCESSORIES / ACCESSOIRES STANDARD

05.5011/1 Nebulizer bulb / Chambre de nébulisation

05.5012/1 Mask adult / Masque adulte

05.5015/1 Tube 210 cm / Tube 210 cm

ON REQUEST / SUR DEMANDE

05.5009 Nebulizer set complete with child face mask

05.5010 Nebulizer set complete with adult face mask

■ F-205

COMPRESSOR NEBULIZER FOR AEROSOL

- It is equipped with piston type compressor. Powerful, silent and reliable.
- ABS case with large built-in accessories compartment.
- Dimensions: 30 x 19 x 16cm

NEBULISEUR POUR AÉROSOLTHÉRAPIE

- Compresseur à piston, puissant, silencieux et à longue durée de vie.
- Cof fret ABS avec compartiment pour accessoires.
- Dimensions: 30 x 19 x 16cm

TECHNICAL SPECIFICATIONS / SPÉCIFICATIONS TECHNIQUES

MODEL	F-205
Weight / Poids	2,3 kg
Power supply / Alimentation	230V~ - 50/60 Hz
Max pump pressure / Pression max del la pompe	2,7 bar
Power consumption / Puissance absorbée	185VA
Nebulization / Nébulisation	2cc/7-8min
Medication cup capacity / Capacité de l'ampoule	10ml

STANDARD ACCESSORIES / ACCESSOIRES STANDARD

05.5011/1 Nebulizer bulb / Chambre de nébulisation

05.5012/1 Mask adult / Masque adulte

05.5013/1 Mask child / Masque enfant

05.5015/1 Tube 210 cm / Tube 210 cm

05.5019/1 Set of 5 filters / Set de 5 filtres

ON REQUEST / SUR DEMANDE

05.5009 Nebulizer set complete with child face mask

05.5010 Nebulizer set complete with adult face mask

■ F-205B

COMPRESSOR NEBULIZER WITH BATTERY / NEBULISEUR AVEC BATTERIE





■ F-202.00

ULTRASONIC NEBULIZER FOR AEROSOL

- Excellent therapeutic performances coupled with an easy use. Fast nebulization, low noise level, excellent micronisation of medication,
- Dimensions: 24,5 x 10 x 19 cm

NEBULISEUR ULTRASONIQUE POUR AÉROSOLTHÉRAPIE

- D'une utilisation extrêmement simple. Garantie une très bonne et rapide nébulisation du médicament dans un silence absolu.
- Dimensions: 24,5 x 10 x 19 cm

TECHNICAL SPECIFICATIONS / SPECIFICATIONS TECHNIQUES

Weight / Poids	600gr
Noise level / Niveau sonore	≤ 55 dBA
Power supply / Alimentation	230V - 50/60 Hz
Medication cup capacity / Capacité de l'ampoule	12 ml
Nebulization / Nébulisation	up to / jusqu'à 2,0 ml/min
Particles / Taille des particules	0,5 - 5 micron
frequency / Fréquence d'oscillation	1,7 MHz

STANDARD ACCESSORIES / ACCESSOIRES STANDARD

- 05.5012/1 Mask adult / Masque adulte
- 05.5013/1 Mask child / Masque enfant
- 05.5021/1 Mouth piece / Embout buccal
- 05.5018.01 Corrugated tube / Tube annelé
- 05.5030.01 Nebulizer bulb / Chambre de nébulisation
- ON REQUEST / SUR DEMANDE
- 05.5009 Nebulizer set complete with child face mask
- 05.5010 Nebulizer set complete with adult face mask



■ F-201.00

COMPRESSOR NEBULIZER FOR AEROSOL

- It is equipped with piston type compressor. Powerful, silent and reliable.
- Dimensions: 22 x 16,5 x 9cm

NEBULISEUR POUR AÉROSOLTHÉRAPIE

- Compresseur à piston, puissant, silencieux et à longue durée de vie.
- Dimensions: 22 x 16,5 x 9cm

TECHNICAL SPECIFICATIONS / SPÉCIFICATIONS TECHNIQUES

Weight / Poids	1,5 kg
Power supply / Alimentation	220V - 50 Hz
Max pump pressure / Pression max del la pompe	2,5 bar
Power consumption / Puissance absorbée	60W
Liter flow range / Débit en litres	5-8 L/min

STANDARD ACCESSORIES / ACCESSOIRES STANDARD

- 05.5011/1 Nebulizer bulb / Chambre de nébulisation
- 05.5012/1 Mask adult / Masque adulte
- 05.5013/1 Mask child / Masque enfant
- 05.5015/1 Tube 210 cm / Tube 210 cm
- 05.5021/1 Mouth piece / Embout buccal
- 05.5022/1 Nasal canula / Embout nasal
- ON REQUEST / SUR DEMANDE
- 05.5009 Nebulizer set complete with child face mask
- 05.5010 Nebulizer set complete with adult face mask



■ 05.5090

AEROSOL MASK

- Tracheostomy mask for 22mm corrugated tubing, Packing: 50 pcs/box.

MASQUE AEROSOL

- Masque de trachéostomie pour tuyau annelé Ø22 mm. Boite de 50 unités.



STANDARD SET

- Aerosol mask, nebulizer bulb and O2-sure flow tubing

SET STANDARD

- Set de nébulisation avec masque, chambre de nébulisation et tubulure.



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Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln und
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ZLG-BS-244.10.08



Product Service

EC Certificate

Production Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex V
(Devices in Class IIa, IIb or III)

No. G2 044963 0035 Rev. 00

Manufacturer:

Fazzini s.r.l.

SS Padana Sup. 317
20090 Vimodrone (MI)
ITALY

Facility(ies):

Fazzini s.r.l.
SS Padana Sup. 317, 20090 Vimodrone (MI), ITALY

**Product
Category(ies):**

Suction pumps, Powered nebulisers, diaphragm, piston and
ultrasonic, Rebreathing bags and anesthesia masks,
Reanimation bags and face masks, Nasal cannula and
connecting tubes for oxygen and aerosol therapy

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex V. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class IIb and III devices an additional Annex III certificate is mandatory. See also notes overleaf.

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Date, 2019-08-27

Stefan Preiß
Head of Certification/Notified Body