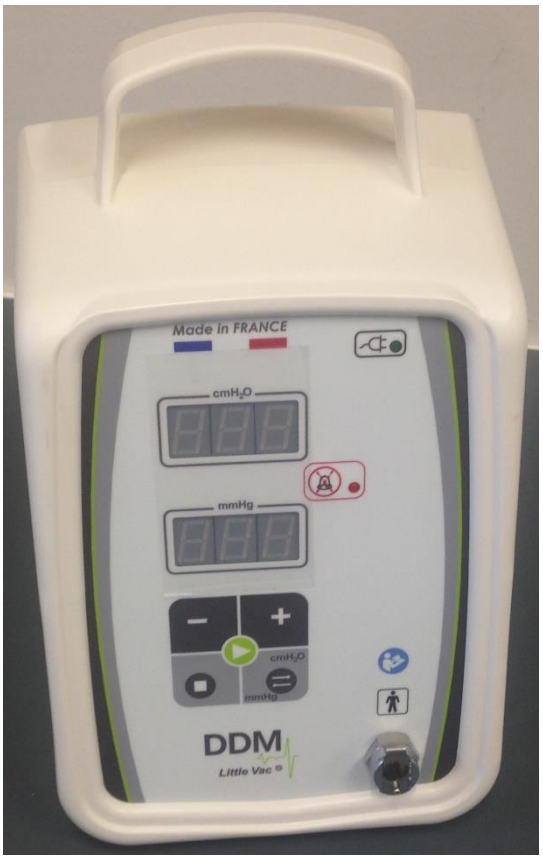
Since 1949

CE 0459

Date of first EC marking certificate: 2020

Aspirator for surgical or biological fluids

References : LV705
Designation : **Aspirator for surgical or biological fluids**



USER GUIDE

Before using these devices for clinical applications, maintenance and troubleshooting please read carefully this manual and understand all information about their features by observing imperatively instructions described.

Dessillons&Dutrillaux
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47240 CASTELCULIER – FRANCE
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ISO 13485 G MED

I. INDEX

II. GENERAL INFORMATIONS

Symbols used

Symbols used	Description	Location
	The operations instructions must be read, written on the back of the appliance	Back of the unit
	Fragile, handle with care	Adhesive package
	Humidity limit	Adhesive package
	Temperature limit	Adhesive package
	Warning message	User guide
	Safety message	User guide
	Separate electronics components from houshold rubbish. This product should be discared at a collection point for recycling of electrical and electronic waste	Identification plate User guide
	Medical device type BF- applied parts constituted by the cuffs and extension in the patient's environment	Front side
	Earth (ground)	Inside the device
	Medical device class IIa complying with the Requirements of Directive 93/42/EEC modified by 2007/42/CEE.	Identification plate
mmHg	Pressure unit is measured in millimetres of mercury (1 mmHg equal to 1.33 hPa - (hectopascal)	Display screen
min	Specified time expressed in min	Display screen
	Fabricant : Dessillons&Dutrillaux Z.I. La Tuque 47240 Castelculier - France	

Intended to use 

The device is designed to operate continuously.
The fluid aspirator is used exclusively in the operating room to aspirate surgical or biological fluids inside a jar under vacuum.

The LittleVac LV705 is a medical device for use with a fluid jar. The various jars of fluids (disposable or reusable) and the tubing constitute the applied parts of the device, used in the environment of the patient and not directly.

These elements are listed in the appendix but are not manufactured or sold by DESSILLONS & DUTRILLAUX.

The companies SERRES and MEDLINE INTERNATIONAL France are 2 manufacturers of jars present on the European market and who market accessories compatible with the LittleVac.

The pressure parameters are defined by practitioners, this manual can in no way replace the techniques usually performed. The usable pressure range is between 0 and -300 mmHg.

Patient population

Any human being can have recourse to a suction of fluids, only a decision of the medical profession can give rise to a rejection of this technique.

User profil

LITTLE VAC is intended to be used only by medical professionals trained accordingly to the intended use, and described below. It is commonly Nurse of Operating Room State graduate or Nurse Anesthetist graduate of State.

Medical contraindication

No contraindication has been found in the clinical literature.

In all cases, the final decision on the use of the device rests with the attending physician.

Medical devices Directive

Medical device class IIa complying with the requirements of Directive 93/42/CEE.

Storage and transport conditions before use

Do not store the package outside, avoid mechanical vibrations.
Storage and transport conditions : temperature -5°C to +50°C relative humidity 20% to 80 % maximum.
Operating conditions : temperature 5°C to +40°C relative humidity 20 % to 80 % maximum.
Handle the package carefully to avoid dropping.

I. GENERAL WARNING

Any modification may cause a hazard to the patient or user. Under no circumstances and in no way the device must not be changed.

Caution

-The environmental conditions of use must be respected.

-To avoid electric shock pneumatic LittleVac LV705 should only be connected to a power network with a protective earth with the power cord of 5 meters provided. It is not permissible to use a base of multiple sockets or extension cord.

-To prevent electrical hazard to the patient, do not use the medical device in the immediate environment of the patient (less than 2 meters).

-Medical device and particularly its electrical connection must be protected from water and moisture. Never turn on the device if the liquid has been spilled on it.

-To prevent risk of damage, do not use metallic or pointed objects to enter display values on keyboards.

-Do not pull on the AC power or pneumatic extensions to change the device instead.

-Any movement of the device must be disconnected for the power supply.

-To avoid the risk of strangulation or patient people, ensure that the power cord or extension tires are in reasonable distance.

- To prevent risk of device falling, do not propel the unit mounted on mobile stand, a handle is provided to make any manoeuvre secure by pulling or pushing the device to cross in front of any obstacles. The moving is done by pushing forward. Keep one hand on the handle in case of uneven ground.

- To prevent inadvertent movement, it is strongly recommended to lock the wheels brakes.

-Separate the electrical power cord to the castors.

-Do not use the device in areas where is risk of explosion induced by anesthetics and disinfectants inflammable.

-Be sure to use accessories in good condition and suitable to members whom they are intended.

-The connector receptacle serves as a connection switch and must remain accessible at all times to enable the immediate disconnection of the power cord in the event of danger.

-For Switzerland, the plug will 12G1011 standard model of FELLER brand and the power cable must be H05VV-F FELLER brand.

Cleaning and disinfection

Disconnect the device from the mains supply before any intervention cleaning and disinfection of the unit, using only appropriate disinfectant wipes (Type Wip'anios). Apply wipe surfaces and extensions to deal with.

In case of severe soiling use a second wipe leaving for 5 to 15 minutes depending on the antimicrobial efficacy sought, however, leaving the screens.
There is no limit to use these applications. Rinsing is unnecessary.

It is also possible to use detergent foam using a non-woven cloth.
Procedure for cleaning the device as indicated for the wipe.

Never spray disinfectant directly on the device.
LittleVac extensions must be dried before use.

Before each commissioning of the device

- Make sure the accessories are compatible for use with pneumatic tourniquet, it is forbidden to use cuff without appropriate connectors and change the output connectors.

-Check that the connexions are in good conditions, that they are not bent or pinched and that the air is output as soon as the system starts up.

-As a precaution to ensure that the medical device works properly and that the system is sealed with the cuff used by proceeding as described below.

- Prepare a fluid jar.

- Display a vacuum setpoint eg 150 mmHg.

- Connect the vacuum cleaner to the canister.

- Start the cycle

- Block the arrival of fluids from the jar

- The pressure indicated by the device must increase

Precautions relating to electromagnetic compatibility

The fluid vacuum cleaner must be installed and put into service in accordance with the EMC recommendations attached in the appendix. The operation of the device is guaranteed for all disturbances below the compliance levels declared in the appendix.

Malfunctions can be caused by the proximity of non-CE portable or mobile RF communications equipment.

In accordance with paragraph 5.2.2.1 (d) of standard IEC 60601-1-2 version 2007, the accompanying documents must include the following information:

The EM device or system should not be used near or stacked with other devices. If it is not possible to do otherwise, the EM device or system should be monitored to verify normal operation in the configuration in which it will be used.

The use of accessories, sensors or cables other than those sold by the manufacturer as replacement parts or internal components can induce an increase in the emission levels or a decrease in the immunity levels of the electro-medical devices.

Electromagnetic conformity established with the following accessories :
Designation
Switching mode power supply card
Power supply cord 5 meters
Connector receptacle CEE 22

Limits use of the medical device

Life time is estimated at 4 years, an appeared malfunction or accidental fall of the medical device requires to inform the biomedical department about risks in order to conduct a comprehensive review of functionality on the device and ensure the integrity of essential performance described below.

Essential characteristics of the medical device

o Vacuuming of a fluid jar according to a value defined by the operator

o Maintaining this pressure for the duration of the intervention

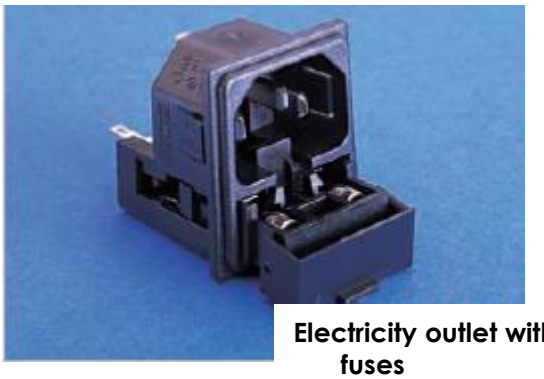
Maintenance

An annual preventive maintenance is recommended for the control of essential performance described below, and electrical safety.

To overcome any malfunction, this service must be performed by Dessillons & Dutrillaux.
The minimum qualification required by maintenance personnel for maintenance operations : biomedical technician level.

Replacing fuses general protection

The fuses power (2 units) are located on the electricity outlet.
Replace them in accordance with the values : FT2A H250V.



Electricity outlet with 2 fuses

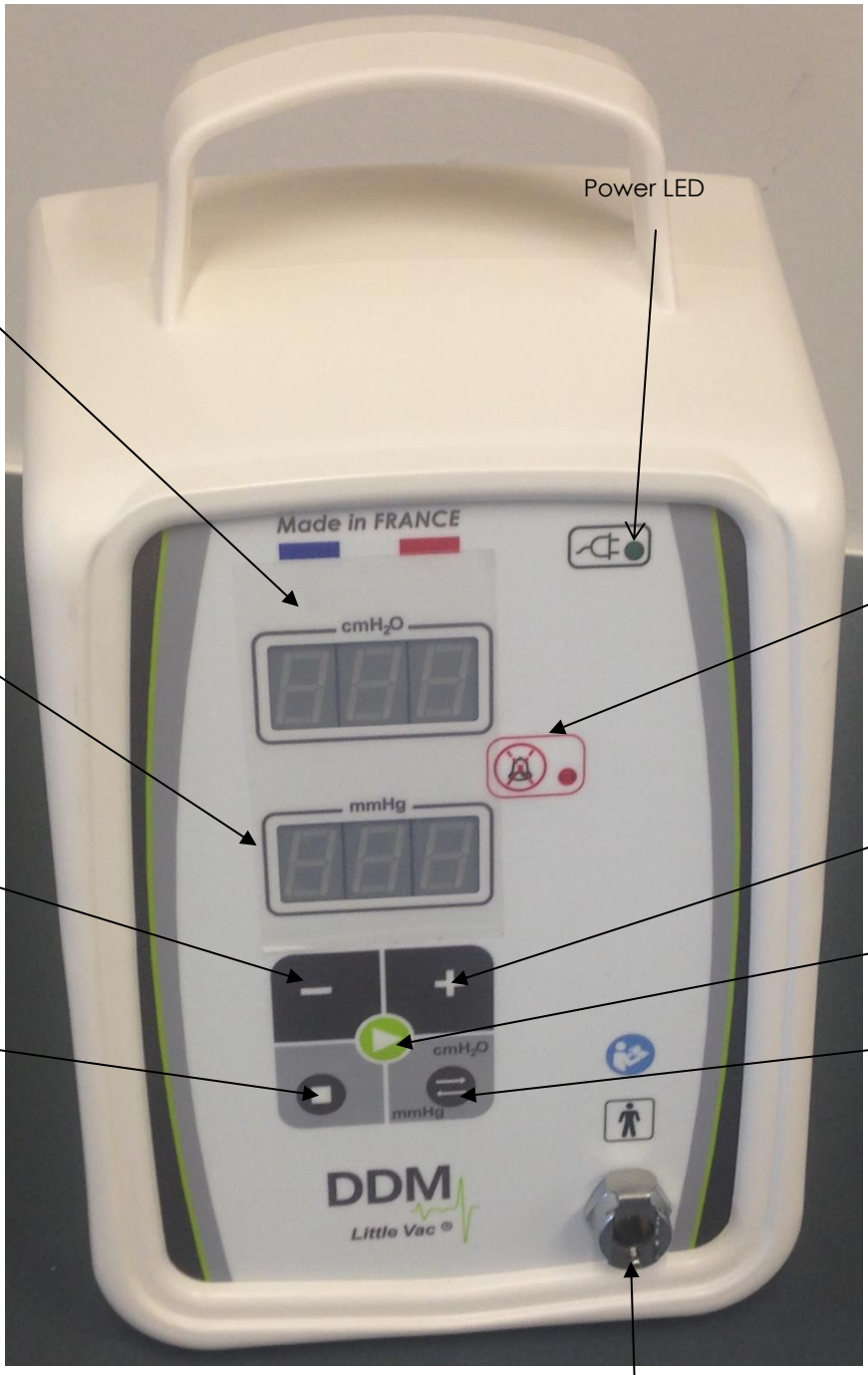
The circuit board is protected by an external fuse : fuse value : F1.6AH250V (rapid action, power cut 1500A).

Borne d'équipotentialité

Equipotential bonding conductor

The equipotential bonding terminal, on the back of the device and symbolized by this logo ⏚ is used in the electrical tests carried out by D & D MEDICAL

II. PRESENTATION OF THE MEDICAL DEVICE (LV705)



Power LED

Digital display of pressuression in cmH2o

Digital display of pressure in mmHg

Stop alarm button with alarm LED

Button LESS

Button PLUS

VALIDATION button

Button STOP

Button Change of unit

Connection coupling for fluid jar

III. ACTIVATION OF THE DEVICE

A. START OF DEVICE

The LittleVac LV705 is operational and switches off by pressing the side switch.
At start-up, a sound is emitted, the alarm LED and the displays light up.
The top display scrolls left to view the software version:

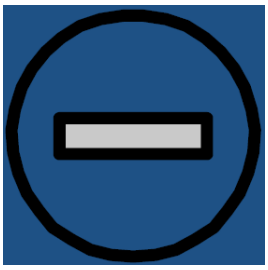
The lower display shows scrolling to the left "INIT":L'afficheur du bas indique en défilement vers la gauche « INIT »:

B. SETTING THE PRESSURE

Changing the pressure (outside off surgery)
The user has to select the pressure parameter, setting a value and validate these instructions to perform a pressurization of the LittleVac LV705.

1) **Press the PLUS or MINUS buttons**

OR



The lower display will be flashing

2) **Keep pressing the + or - button until the desired value**

3) **Validation**

By pressing VALIDATION :

The lower display stops flashing

Info : By waiting 5 seconds the user can validate information entered.

4) **Example 150 mmHg**

Press the buttons  or  to  confirm by pressing the button  or wait 5 seconds

Changing the pressure (during surgery)

1) **Press the PLUS or MINUS button**
2) **Keep pressing the + or – button until the desired value**
3) **Validation (by pressing VALIDATION button)**
4) **Example 280 mmHg**

Press the buttons boutons  or  to  , confirm by pressing the button  .

Note : Wait for the flashing to stop (5 seconds), does not validate the pressure change, only pressing VALIDATION button validate setting.

C. SYSTEM SHUT-DOWN

Launching a pressure cycle (aspiration)

When the pressure setpoint is set on the circuit and therefore there is no display flashing. The vacuum cycle can be started by pressing the VALIDATION button.

End of pressure cycle (venting)

- At the end of use, the user has to press the key  during 1 second to perform the venting of the jar.
- Stop the pump, then vent the jar.
- Stop the cycle alarm.

IV. Information about operation

A. KEYBOARD MANAGEMENT

Conditions for taking into account the pressing buttons :

- The keys  ,  ,  ,  and  are taken into account by pressing.
- The key  is taken into account at the end of a second.

B. DEFAULT MANAGEMENT

Conditions for triggering an alarm

Alarm		Causes	Priority	Actions
Flashing of the top or bottom display (depending on the unit setting)	+ 7 bips	Overpressure: Display of vacuum above the set pressure and not stabilized for 5 seconds	High	Check that there is no element blocking the arrival of fluids
Flashing of the top or bottom display (depending on the unit setting)	+ 7 bips	Failure to vacuum the jar	High	Check that the jar is airtight

The visual alarm also includes led light, flashing with the tempo of the audible alarm.

For the operator, the perception of a visual alarm condition can be established only being in front of the device, to overcome this requirement LittleVac LV705 is equiped with an audible alarm signal.

Alarm deactivation :

In case of high prority alarm, by pressing the key  the user disables the alarm tone during 30 seconds, during this time the visual alarm is always displayed.

In case of medium priority alarm, pressing the key  stops current alarm.

If there is an electrical power failure, the alarm system is immediatly unable to restore the alarm settings.

In case of power failure, the alarm is no longer functional.

V. CONFIGURATION

A. MAINTENANCE

A menu protected by a password is accessible via a specific hardware configuration.
Only a qualified technician Dessillons & Dutrillaux can intervene on the settings of the device.

This menu allows :

- Set the calibration of pressure sensors.
- Check the configuration of the pneumatic tourniquet

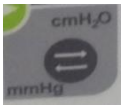
B. USER SETTING

Volume setting :

The user can adjust the volume level of the device, it will be saved and re-applied at every boot.
To adjust the volume, proceed as follows :

1) **Being out of operation cycle**
2) **Holding down the button "STOP ALARM"** 
3) **Keep pressing buttons**  **or**  **until the volume desired value.**
4) **Wait 2 secondes to confirm**

Pressure unit setting :

1) **Being out of operation cycle**
2) **Press the button** 

VI. USE WITH A FLUID JAR

A. INSTRUCTIONS FOR USING THE DEVICE WITH A FLUID JAR

1) **Connect the power cord to the power grid**

Press the switch ON / OFF to turn on the device.

2) **Put the tube on the jar**

Connect the tubing to the fluid jar.

3) **Connect the jar connecting tube**

With the quick coupler of the device, taking care that the tubing is not bent, bent, pinched and that no knot could hinder the depression of the jar.

4) **Proceed with the placement of the suction tube on the endoscope**

Connect the suction inlet of the jar to the endoscope or the suction tool.

5) **Pressure set adjustment**

By proceeding as described in paragraph V-B, ensuring that the suction is carried out correctly.

6) **At the end of using the device Ultimately, vent the circuit**

Pressing the key STOP.

VII. ANNEX

Technical charactéristicsof LittleVac LV705

STORAGE CONDITIONS	T : -5°à 40°C, Humidity : 20- 80 %
CONDITIONS OF USE	T : 5°à 40°C, Humidity : 20 – 80 % Maximum altitude 2000 m Atmospheric pressure 79.0 kPA to 106 kPa
CASE MATERIALS	ABS (Acrylonitrile Butadiene Styrene)
Density	1.112 g/ cm^3
Shock resistance	> 25 KJ / m^2
UL flammability test	UL94 V-0
Heat stability	85°C
DIMENSIONS	Modulofuse
Height (mm)	238
Width (mm)	167
Depth (mm)	160
WEIGHT kg	2.200
Dimensions of the display	
Width (mm)	38.4
Height (mm)	16.4
Quantity	2
LINE VOLTAGE	100 - 240 V AC
LINE FREQUENCY	50 – 60 Hz
POWER PLUG	60 VA
SWITCH MODE POWER SUPPLY	Entry : 90-264 Vac, 47-63 Hz, 1.8 – 1 A - Exit : 15 Vdc, 4A
FUSE	
Input power card	FTT2AH/250V
Output power card	F1,6AH/15V
PUMP	
Type	Membrane pump
Pump flow	4.6 l/mn
PRESSION	
Type	mmHg
Service	1.7 bar
Setting range	0 to 300 mmHg
Setting precision	± 1 mm Hg
Display accuracy	± 5 mm Hg
Alarm	An audible and visual alarm
Number of independant pressure circuit	1
CONNECTION	
Pneumatic	1 female coupler CPC type
Electric	Connector CEE22
MAXIMUM SOUND LEVEL WHILE FUNCTIONING	52 dB

DIRECTIVES AND DECLARATION OF THE MANUFACTURER - ELECTROMAGNETIC IMMUNITY

LITTLE VAC LV705 is entended to be used in the electro-magnetic environment detailed below. It is convenient that the user of these devices makes sure that they are used in such an environment.

Immunity testing	Level of testing in accordance with CEI 60601-1-2:2014	Level of conformity	Electromagnetic environment - directives
Conducted RF disturbances EN 61000-4-6	3 Veff of 150 kHz at 80 MHz outside ISM tapes	3 Veff	It is convenient that portable instruments and RF mobile devices are not too close to any part of these devices, including cables; it is advisable to respect the recommended separation distance, calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** *d* = [3.5/ *3*] *?P* *d* = [3.5/ *3*] *?P* of 80 MHz at 800 MHz
Radiated RF disturbances EN 61000-4-3	3 V/m of 80 MHz at 2.5 GHz	3 V/m	*d* = [7/ *3*] *?P* of 800 MHz at 2,5 GHz where *P* is the characteristic of the maximum output power of the transmitter in watts (W), according to the manufacturer of the transmitter and *d* is the recommended separation distance in meters (m). It is convenient that the field intensity of the RF fixed transmitters, determined by an electromagnetic research on site(a), are less than the level of conformity, in each frequency band(b).

NOTE 1: At 80 MHz and at 800 MHz, the highest frequency band is applied.

NOTE 2: These directives may not be applicable in every situation. The electromagnetic propagation is affected by the absorption and by the reflection of structures, objects and people.

(a) The field intensity of the fixed transmitters, such as the base stations for radiotelephones (mobiles/wireless) and land mobile radios, amateur radios, radio broadcasting and TV broadcasting cannot be theoretically planned with accuracy. In order to evaluate the electromagnetic environment due to fixed RF transmitters, it is convenient to consider an electromagnetic research on site. If the field intensity, measured in the place where the devised is **used, exceeds the RF level of conformity applicable above, it is advisable to observe the device to make sure that** it works normally. If abnormal performances are observed, additional measures may be taken, for the reorientation or reposition the device.

(b) In the band frequency of 150 kHz to 80 MHz, it is convenient that the field intensities are less than **3 V/m**.

RECOMMENDED SEPARATION DISTANCES BETWEEN PORTABLE INSTRUMENTS AND RF MOBILE DEVICES AND LITTLE VAC LV705

LITTLE VAC LV705 is aimed to be used in an electromagnetic environment where radiated RF disturbances are under control. The user of these devices may help to prevent electromagnetic interferences by keeping a minimal distance between portable instruments and RF mobile devices (transmitters) and these devices, as recommended below, according to the maximum emission power of the communication device.

	Separation distance according to the frequency of the transmitter **M**		
Maximum emission power assigned of the W **transmitter**	**from 150 kHz to 80 MHz** *d* = [3.5/ *3*] ?*P*	**from 80 MHz to 800 MHz** *d* = [3.5/ *3*] ?*P*	**from 800 MHz to 2.5 GHz** *d* = [7/ *3*] ?*P*
0.01	0.12	0.12	0.23
0.1	0.37	0.37	0.74
1	1.17	1.17	2.33
10	3.69	3.69	7.38
100	11.7	11.7	23.3

In the case of transmitters which have a maximum emission power assigned that is not indicated below, the recommended separation distance *d* in meters (m) may be determined by using the equation applicable to the frequency of the transmitter, where *P* is the characteristic of the maximum transmission power of the transmitter in watts (W), according to the manufacturer of the transmitter.

NOTE 1: At 80 MHz and at 800 MHz, the separation distance for the highest frequency band is applied.

NOTE 2: These directives may not be applicable in every situation. The electromagnetic propagation is affected by the absorption and by the reflection of structures, objects and people.

GUIDANCE AND MANUFACTURER'S DECLARATION - ELECTROMAGNETIC EMISSIONS

LITTLE VAC LV705 is provided for use in the electromagnetic environment specified below. He agreed that the customer or the user of these devices ensure that they are used in such an environment.

Emissions test	***Conformity***	***Electromagnetic environment - directives***
Emissions RF *CISPR 11*	*Group 1*	*LITTLE VAC LV705 uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.*
Emissions RF *CISPR 11*	*Class B*	
Harmonic emissions *EN61000-3-2*	*Class A*	*LITTLE VAC LV705 is suitable for use in all premises, including domestic establishments and those directly connected to public low-voltage power supplies buildings used for domestic purposes.*
Emissions of voltage fluctuations flicker *EN 61000-3-3*	*Conform*	

TABLE MANUFACTURER'S INSTRUCTIONS AND DECLARATION - ELECTROMAGNETIC IMMUNITY FOR ALL DEVICES AND EM SYSTEMS OTHER THAN MAINTAINING LIFE

Directives and declaration of the manufacturer – electromagnetic immunity			
LITTLE VAC LV705 is intended to be used in the electro-magnetic environment detailed below. It is convenient that the user of these devices makes sure that they are used in such an environment			
Immunity testing	**Level of testing CEI 60601-1-2:2014**	**Level of conformity**	**Electromagnetic environment - directives**
Electrostatic discharge (DES) EN 61000-4-2	±6 kV in contact ±8 kV in air	±6 kV ±8 kV	It is advisable that the floors are made of wood, concrete or ceramic tiles. If the floors are covered with synthetic materials, it is convenient that the relative humidity is of at least 30%.
Electrical Fast transient / burst EN 61000-4-4	±2 kV for electric lines ±1 kV for input/output lines	±2 kV Non applicable	It is advisable that the quality of the power supply network is that of a typical commercial or hospital environment.
Impulse waves EN 61000-4-5	±1 kV differential mode ±2 kV common mode	±1 kV ±2 kV	It is advisable that the quality of the power supply network is that of a typical commercial or hospital environment.
Voltage dip, brief voltage outsets and voltage variation in the power supply input lines EN 61000-4-11	<5 % *U*T for 10 ms 40 % *U*T for 100 ms 70 % *U*T for 500 ms <5 % *U*T for 5 s	<5 % *U*T for 10 ms 40 % *U*T for 100 ms 70 % *U*T for 500 ms <5 % *U*T for 5 s	It is advisable that the quality of the power supply network is that of a typical commercial or hospital environment. If the user of these devises requires the continuous operation during the power cuts in the supply network, it is advisable to feed these devices by means of a power supply without cuts or a battery.
Magnetic field at the frequency of the electric network (50/60 hertz) EN 61000-4-8	3 A/m	3 A/m	It is advisable that the magnetic fields at the frequency of the electric network have the levels of a representative place located in a typical commercial or hospital environment.
NOTE : *U*T is the voltage of the alternative network before the application of the level of testing			

Declaration of conformity DIR/93/42/CEE

DDM DESSILLONS & DUTRILLAUX	**DECLARATION DE CONFORMITE** selon la directive 93/42/CEE modifiée par la directive 2007/47/CEE **DECLARATION OF CONFORMITY** *According to directive 93/42/EEC modified by directive2007/47/EEC*	Indice 3

Nous, DESSILLONS & DUTRILLAUX
Z.I. de la Tuque
47240 CASTELCULIER
France

Déclarons sous notre entière responsabilité que le ou les dispositifs médicaux décrits ci-dessous sont conformes aux exigences de la directive 93/42/CEE, modifiée par la directive 2007/47 CE, qui leurs sont applicables.
We declare under our responsability that the products or product groups described below conform to the requirements of the European Directive 93/42/EEC, modified by the Directive 2007/47 EEC applicable at materiel devices.

DISPOSITIF MEDICAL : *Medical Device Group :* *Code GMDN :*	**LittleVac** *LittleVac* *36776*
INDICE DE CLASSEMENT : selon annexe IX de la directive *Index of classification :* *Appendix IX, of the European directive*	**Classe IIa, règle 11** *Class IIa, rule 11*
Procédure de marquage CE : *CE marking process*	**Annexe II.3**
MARQUAGE CE : *CE marking :*	**CE 0459**

Cette déclaration est basée sur les éléments suivants :
This declaration is based on the following elements:

- **Documentations techniques (réf LittleVac) démontrant la conformité des dispositifs médicaux aux exigences de la directive**
  Technical documentation (ref. DTC Little Vac) showing the conformity of these devices to the requirements of the directive.

- **Certificat CE d'approbation du système de management de la qualité de DESSILLONS & DUTRILLAUX n° 32763 rev 4 émis par LNE/G-MED :**
  CE certificate n° 32763 rev 4 of approval of the system of management of the quality of DESSILLONS & DUTRILLAUX emitted by LNE/G-MED

ORGANISME NOTIFIE CE n°: 0459 **LNE GMED – 1 Rue Gaston Boissier – 75724 PARIS CEDEX 15**
Notified Body number 0459

Date : 06/04/2021

Vanessa HILBERT / Responsable Qualité
DESSILLONS & DUTRILLAUX
47240 - CASTELCULIER

CE marking

GMED
GROUPE LNE

ATTESTATION / *CERTIFICATE* **N° 32763 rev. 4**
Délivrée à Paris le 19 mars 2021
Issued in Paris on March 19th, 2021

ATTESTATION CE / *EC CERTIFICATE*

Approbation du Système Complet d'assurance Qualité/ *Approval of full Quality Assurance System*
ANNEXE II excluant le point 4 Directive 93/42/CEE relative aux dispositifs médicaux
ANNEX II excluding section 4 Directive 93/42/EEC concerning medical devices
Pour les dispositifs de classe III, un certificat CE de conception est requis
For class III devices, a EC design certificate is required

Fabricant / *Manufacturer*

DESSILLONS DUTRILLAUX
ZI La Tuque
47240 CASTELCULIER FRANCE

Catégorie du(des) dispositif(s) / *Device(s) category*

Manchette à pression, garrots électro-pneumatiques et électroniques à pression constante avec option LOP, aspirateurs de fluides chirurgicaux ou biologiques

Pressure cuff, electronic and electro-pneumatic tourniquets with constant pressure with option LOP, aspirators for surgical or biological fluids

Voir document complémentaire GMED / See GMED additional document
n° 38203

GMED atteste qu'à l'examen des résultats figurant dans le rapport référencé P600792, P601429, le système d'assurance qualité - pour la conception, la production et le contrôle final - des dispositifs médicaux énumérés ci-dessus est conforme aux exigences de l'annexe II excluant le point 4 de la Directive 93/42/CEE.

GMED certifies that, on the basis of the results contained in the file referenced P600792, P601429, the quality system - for design, manufacturing, and final inspection - of medical devices listed here above complies with the requirements of the Directive 93/42/EEC, annex II excluding section 4.

La validité du présent certificat est soumise à une vérification périodique ou imprévue
The validity of the certificate is subject to periodic or unexpected verification

Début de validité / *Effective date* : **March 19th, 2021 (included)**
Valable jusqu'au / *Expiry date* : **May 26th, 2024 (included)**

GMED - 32763 rev. 4
Modifie le certificat 32763-3

GMED
DocuSigned by:
Lionel DREUX
Lionel DREUX
Certification Director

Ce document complémentaire GMED n° 38203 rev. 0 atteste de la validité du certificat CE n° 32763 rev. 4 au regard des informations listées ci-dessous.

This GMED additional document n° 38203 rev. 0 attests to the validity of CE certificate n° 32763 rev. 4 with regard to the information listed below.

Fabricant / *Manufacturer:*

DESSILLONS DUTRILLAUX
ZI La Tuque
47240 CASTELCULIER FRANCE

Identification des dispositifs / *Identification of devices*

Désignation du dispositif / Accessoires marqués CE *Device designation / CE marked accessories*	Réf commerciale du dispositif ou code article *Device commercial reference or article code*	Classe du DM *MD class*
Manchette à pression BLUE FUSE 500 cc	M20085	IIa
Manchette à pression BLUE FUSE 1000 cc	M20080	IIa
Manchette à pression BLUE FUSE 3000 cc	M20075	IIa
Manchette à pression CLEAR FUSE 500 cc	M30500	IIa
Manchette à pression CLEAR FUSE 1000 cc	M31000	IIa
Manchette à pression CLEAR FUSE 3000 cc	M34000	IIa

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Certification Director

Désignation du dispositif / Accessoires marqués CE *Device designation / CE marked accessories*	**Réf commerciale du dispositif ou code article** *Device commercial reference or article code*	**Classe du DM** *MD class*
Manchette à pression EASY FUSE 500 cc	**M10500**	**IIa**
Manchette à pression EASY FUSE 1000 cc	**M11000**	**IIa**
Manchette à pression EASY FUSE 3000 cc	**M13000**	**IIa**
Manchette à pression GREY FUSE 500 cc	**M20500**	**IIa**
Manchette à pression GREY FUSE 1000 cc	**M21000**	**IIa**
Manchette à pression GREY FUSE 3000 cc	**M23000**	**IIa**
Manchette à pression GREY FUSE 5000 cc	**M25000**	**IIa**
Garrot électro-pneumatique Little Pump à 1 circuit de pression régulée	**G10705**	**IIa**
Garrot électro-pneumatique Little Pump dual à 2 circuits de pression régulée	**G10706**	**IIa**
Garrot électronique Easy Pump à 1 circuit de pression régulée	**G10803**	**IIa**
Garrot électronique Easy Pump dual à 2 circuits de pression régulée	**G10903**	**IIa**
Aspirateur de fluides chirurgicaux ou biologiques LITTLE VAC	**LV705**	**IIa**

Site couvert et Activités / *Location and Activities*

DESSILLONS DUTRILLAUX - ZI La Tuque - 47240 CASTELCULIER - FRANCE
Siège social – responsable de la mise sur le marché, conception, fabrication et contrôle final
Headquarters – legal manufacturer, design, manufacture and final control

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Certification Director

ACCESSORIES AND CONSUMABLES LIST

ACCESSORIES	
Réf	Désignation
No communicated	Suction jar 1 000 ml
No communicated	Suction jar 2 000 ml
No communicated	Suction jar 3 000 ml
No communicated	Suction tubes