

Regulatory information

CE Marking	Index of classification	PHTHALATES LATEX
CE	I	

Manual pneumatic tourniquets are made up of :
 Manometer 0-600 mmHg with hand inflator
 Decontaminable arm cuff and lower limb cuff without bladder.

The manometer is graduated from 0 to 600 mmHg with a graduated measuring range every 10 mmHg, and an accuracy of ± 5 mmHg.

The manometer made up of a membrane aneroid beryllium copper treated with quality watch-making mechanism.

These arm cuffs and lower limb cuffs of very robust design are composed of a single monobloc assembly, which facilitates their maintenance and decontamination. Owing to their impervious connector, it is possible to immerse them in a decontaminating solution.

1 – Device identification



Manual tourniquet with decontaminable monobloc arm cuff

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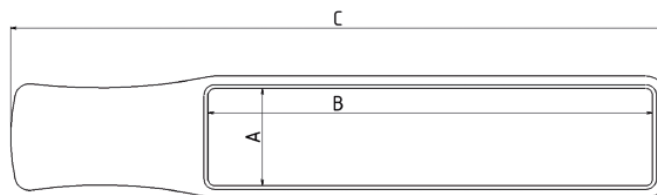
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Date of first EC marking certificate :
 2004

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2 - References

Reference	Designation	Dimensions in cm		
		A	B	C
A10657	Manometer			
GMBM01	Manual tourniquet arm cuff/lower limb cuff New born	3.5	29	38
GMBM02	Manual tourniquet arm cuff Child	4.5	35	48
GMBM03	Manual tourniquet arm cuff Small adult	6	46	61
GMBM04	Manual tourniquet arm cuff Adult	8	46	67
GMBM05	Manual tourniquet conical arm cuff Adult L	10	47	70
GMCM04	Manual tourniquet conical lower limb cuff Adult	10	62	76
GMCM05	Manual tourniquet conical lower limb cuff Adult L	10	76	90
GMCM06	Manual tourniquet conical lower limb cuff Adult XL	10	82	100
GMCM07	Manual tourniquet conical lower limb cuff Adult XXL	10	107	122
KGMBM1	Manual tourniquet with 1 arm cuff Child, adult and 1 lower limb cuff adult L			
KGMBM2	Manual tourniquet with 1 adult and 1 lower limb cuff adult L			



A : Bladder width - B: Bladder length - C : Overall length

3 – Use of the device – Operating instructions

- **Application of the arm cuff or lower limb cuff on the limb :**

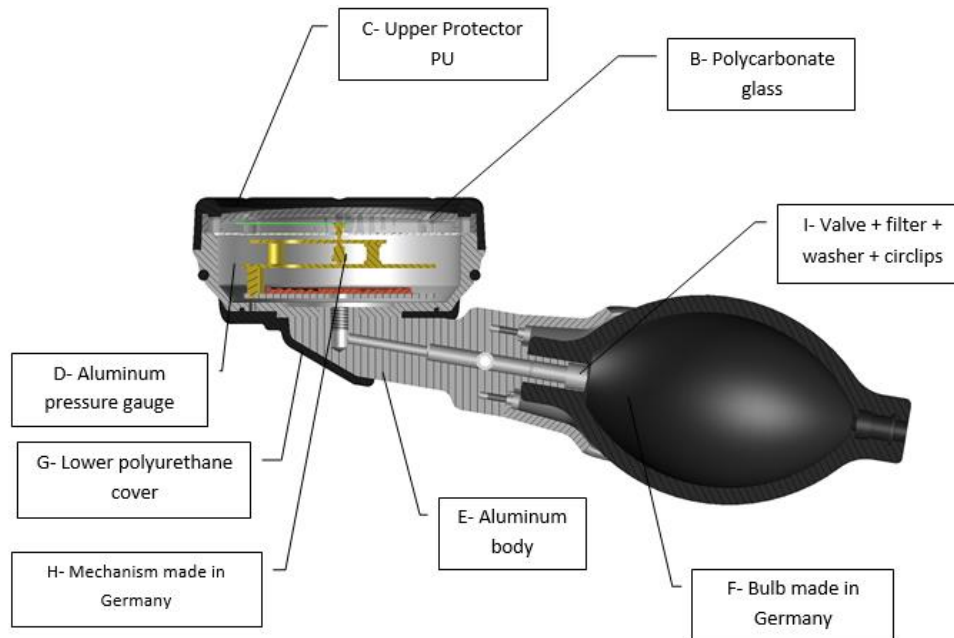
- Exsanguinate the limb using an Esmarch bandage or by elevating at 45° for 5 to 8 min.
- Before fitting the tourniquet:
 - check that the tourniquet to be fitted is of the correct size for the limb
 - check that the pocket of the tourniquet is sealed
 - check the quality of the Velcro and seams on the arm cuff / lower limb cuff
- Position the arm cuff or lower limb cuff on a protective bandage, previously applied on the skin of the limb on which the tourniquet is to be fitted.
- Secure the whole by making a knot with the ribbon.
- Insert the connecting tube fully (click) in the quick coupler.
- Before applying pressure, pull gently on the tube to check for perfect connection of the 2 parts.

- **Application of the arm cuff or lower limb cuff on the limb :**

- - Connect the pneumatic extension of arm cuff or lower limb cuff in the manometer's connector.

4 - Identification and characteristics of different subsets

Identifiant	Reference	Designation	Characteristic
A		Monobloc cuff	High frequency welded PU fabric
B	A10362	Glass	Polycarbonate
C	A10363	Upper protector	Polyurethan
D	A10364	Pressure gauge	Aluminium
E	A10365	Body	Aluminium
F	A10226	Bulb	Phtalates - free PVC
G	A10366	Lower cover	Polyurethane
H	A10374	Mechanism 0-600 mmHg	Brass
I	A10368	Valve + filter + washer + circlips	



5 - Cleaning and disinfection

N°	Step	Objective	Products used	Duration	Appropriate conditions	Instructions for use
1	Pre-treatment	Facilitate the cleaning step	ANIOSYME DD1	5 min	Dose of 25 ml to 5 liters of cold or	1-1 Prepare a dip tank 1-2 Submerge the medical device 1-3 Rinse with tap water
2	Cleaning	Pre-disinfection	ANIOSYME DD1	5 min	Dose of 25 ml to 5 liters of cold or lukewarm water	2-1 Prepare a dip tank 2-2 Submerge the medical device 2-3 Cleaning with a soft brush or towels 2-4 Rinse with tap water 2-5 Wipe with a clean towels
3	Chemical disinfection	Disinfection	STERANIOS 2 %	15 min	No dilution solution ready	3-1 Prepare a dip tank 3-2 Submerge the medical device and cover the dip tank 3-3 Rinse the device with sterile or filtered 3-4 Wipe with a clean towels
5	Storage area	Conservation of the device to use new	Package for use in the operating room	6 months	Disposable packaging	Keep the medical device as aseptically as possible

➤ Manometer :

- Spray disinfecting solutions. Do not use detergent, do not immerse.

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6 - Maintenance :

Control calibration every 12 months for the manometer.

7-Packaging

Reference	Packaging unit
GMBM01	1
GMBM02	1
GMBM03	1
GMBM04	1
GMBM05	1
GMCM04	1
GMCM05	1
GMCM06	1
GMCM07	1
KGMBM1	Manual tourniquet with 1 arm cuff Child, adult and 1 lower limb cuff adult L
KGMBM2	Manual tourniquet with 1 adult and 1 lower limb cuff adult L

7 - Storage

Type of packaging	Storage area	Temperature	Humidity	Atmospheric pressure
Original packaging	Ventilated area	-10° to 40 ° c	30 to 40 %	500 to 1060 hpA

8 - Warranty

This warranty provides assurance for the customer who purchases a D & D product that should the product fail to function to D & D published specifications during the term of this warranty, will either replace or repair.

The guarantee period is 2 (two) years from the date of purchase.

The product must be used in accordance with its labeling and may not be altered or subjected to misuse, abuse, accident or improper handling.