TECHNICAL DATA SHEET

REUSABLE SPO2 SENSOR - FINGER CLIP - ADULT

PHILIPS COMPATIBLE

FAST TECHNOLOGY

PART NUMBER 90380ME

Remark : According to the Medical device (DM) this file concerns a part number, a type or a range of Medical Device (DM).

1. Administravive information about the company Update date : 19/02/2018

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2. Information about the device or equipment

21	Common name : according to the Europharmat classification	REUSABLE SPO2 SENSOR - FINGER CLIP - ADULT
22	Description : Patient type	REUSABLE SPO2 SENSOR - FINGER CLIP - ADULT ADULT
23	Compatibility	PHILIPS (Monitorage) : C3,EFFICIA (Série CM),M3/M4,MMS,MP 30,MP 40,MP 50,MP 60,MP 70,MP 90,MP2,MP20,MX700,VM4,VM6,VM8,VS3 / PHILIPS (Défibrillateurs) : HEARTSTART MRx/MRxE M3535A/M3536A/M3536J,HEARTSTART XL+,HEARTSTREAM HEARSTART XL M4735A / PHILIPS (Cardiotocographes) : Avalon FM 30,Avalon FM 40-50 / GOLDWAY PHILIPS COMPAGNIE : G3,G30,G40,G60,G70,G80,UT4000A,UT6000A
	Connection	ADULT
24	LPPR* code (ex TIPS if applicable) :	N/A
25	MD Class : Applicable EC Directive: Acoording to the Annexe N° of the notified body: Standard compliance Number of the certifying body LNE Report Manufacturer of the medical device Date of first placing on the market in the EU:	II b 93/42 EEC Annexe II EN 1041 EN ISO 10993-1 EN ISO 10993-5 EN ISO 10993-10 EN ISO 14155 EN ISO 14971 EN ISO 15223-1 EN ISO 17664 IEC 60601-1 Edition 3.1 IEC 60601-1-2 Edition 3.0 IEC 60601-1-6 Edition 3.1 IEC 60601-1-11 EN 62366 TUV N° 0123 ENVITEC
26	Description of the device Dimension Weight (g) Picture	 L=1.50m 123 Monitor side Patient side 
27	Catalogue part number : MANUFACTURER PART NUMBER : N° OEM PART NUMBER : N° Packaging : Unit of order : Qty, Type Multiple of the unit : Qty, Type Minimum quantity of delivery : Qty , Type Part number specifications : Unit, Value	 90380ME F-2414-15 1 SENSOR 1 1 1 SENSOR
28	Composition of the device and accessories ELEMENTS : MATERIAL : Presence of latex Presence of phtalates (DHP) Presence of product from animal or biological origin	 The sensor does not contain any latex. The materials used for manufacturing of the sensor contain no natural rubber latex protein. The materials that come into contact with the patient have undergone a biocompatibility testing. Further information is available on request. NO NO NO

29	**Field- Indications (according to the Europharmat list)**	The sensor is indicated for continuous, non-invasive or spot check monitoring of functional oxygen saturation of arterial haemoglobin (SpO2) and the pulse rate of patients in hospitals, hospital-type facilities or home environments. This SpO2 sensor must only be used under the conditions specified in the system's technical specifications and in conjunction with recommended and approved monitors and oximetry modules. The sensor might not function properly when used in conjunction with non-compatible components. Proper operation must be verified as described in the pulse oximeter manual. Please refer to the relevant monitor / oximetry module manual for additional instructions and safety information.
3. Sterilization process :		
	Sterile device : YES NO	NO
	Sterilization method of the device : Cleaning and disinfection process:	NA Disconnect the sensor from the monitor before cleaning or disinfecting. • The sensor is not autoclavable and cannot be immersed in liquids or cleaning agents. Do not sterilize with ETO method. Follow the cleaning and disinfection method on the IFU. •The sensor must be carefully cleaned or disinfected after every use and before use with a different patient. • Clean the sensor and contact surface with a soft cloth, if necessary moistened with water or mild soap. The product "Klenzyme 1" is recommended for cleaning. • Disinfect the sensor by wiping the sensor body and contact surfaces with a 70% isopropyl alcohol solution. For highlevel disinfection, the product "CIDEX OPA 2" is recommended. Follow the manufacturer's instructions for use.
4. Conditions of preservation and storage		
	Normal conditions of preservation and storage Special cares Validity duration of the product Presence of temperature indicators if necessary	• In order to ensure the correct and safe operation of the product, it must be carefully and properly transported, stored and operated (see instructions on the packaging). • Do not use sensors if damaged. • Check sensor and application at least every 4 hours for proper functioning (check position and patient skin for damage). Reposition, if necessary. Ensure correct positioning of the finger clip. • Depending on their state of health and skin condition, some patients might react to the sensor materials. • Do not autoclave or immerse in liquid or cleansers of any kind. The product may not be sterilised with the ETO process. Follow the instructions for cleaning and disinfection.
5. Safety of use		
51	**Technical safety** : Sources of interference	The following objects / conditions have the potential to interfere with the sensor's proper functioning and to cause it to incorrectly measure SpO2. • The product is not recommended for use near imaging equipment such as magnetic resonance imaging (MRI) units, etc. • Strong sources of electromagnetic interference, e.g. electrical surgical instruments • Strong ambient light and direct light, including infrared and UV light (if required, cover sensor) • Intravascular dyes, nail varnish and artificial fingernails • Strong movements (where relevant, consider coiling the sensor cable into a loop to take the strain off the cable and fasten to patient/subject using a plaster)
52	**Biological safety (if needed) :**	

6. Use advice		
61	**Instructions for use :**	Using the sensor 1. Position the sensor in a suitable location, such as on the index finger or on the thumb, big toe or little finger. 2. Affix the sensor as shown in the figure. The finger of the patient must be inserted up to the end of the sensor. Run the cable along the finger and parallel to the arm. If necessary, use tape to hold it in place. 3. Connect the sensor cable to the patient cable or monitor, and check the functioning according to the monitor manual.
62	**Indications : (EC marking destination)**	CLICK HERE
63	**Precautions of use :**	A correct measurement is not possible when the sensor is connected to an incompatible monitor. The measurement result may deviate significantly from the actual measurement values. Possible damage Connecting incompatible system components can result in damage to the sensor and/or monitor. Selection and suitability of the sensor The sensor must be individually selected for each patient group and in consideration of the body weight limits. The method of application to a finger or foot can be seen in Fig. 1. The sensor is suitable for patients with a body weight of at least 20 kg. Using the sensor 1. Position the sensor in a suitable location, such as on the index finger or on the thumb, big toe or little finger. 2. Affix the sensor as shown in the figure. The finger of the patient must be inserted up to the end of the sensor. Run the cable along the finger and parallel to the arm. If necessary, use tape to hold it in place. 3. Connect the sensor cable to the patient cable or monitor, and check the functioning according to the monitor manual. The sensor reading will only be accurate if the sensor is correctly positioned. If attached incorrectly, the sensor's light signal will not be aimed straight at the tissue, which will affect the SpO2 reading.
64	**Contraindications :** Absolute and relative.	CLICK HERE
7. Further information about the product		
	Bibliography, report of clinical tests, or pharmaco-economic studies	
8.List of annexes (if necessary)		
	Labelling and traceability label (if necessary)	Product reference and the serial number are printed on the sensor for the traceability
9. Warranty		
	The product is guaranteed for **1 year** against manufacturing defects. The defects and the deteriorations caused by the natural wear or by an outside accident, or by the modification of the product not planned or not specified by the seller, are excluded from the guarantee. The products have to be returned in their original packaging without apparent dammage.	