

EC DECLARATION OF CONFORMITY

We, SCW Medicath Ltd., official address: No.4, Baolong 6th Road, Baolong Industrial Town, Longgang District, Shenzhen, China (Postcode: 518116) hereby declare under our own responsibility that the following product(s):

Please refer to the Annex A-List of devices attached to this declaration

meet(s) the provisions of the Council Directive 93/42/EC and the essential requirements which apply to them (it).

The above mentioned device(s) has(ve) been classified as class show in the list annexed to this Declaration as well as the rules devices according to.

This declaration is supported by the Quality Management System certification, certificate registration No. is SX 60101921 0001 according to EN ISO 13485:2012 and EN ISO 13485:2012/AC:2012 issued by TÜV Rheinland LGA Products GmbH, Tillystraße 2, 90431 Nürnberg, Deutschland.

This declaration is based on the conformity assessment of products to the requirements of Annex(es) II, excluding Section 4.

according to the EC Conformity Certificate Registration No.: HD 60101918 0001 issued for the first time on 09/07/2015 and delivered by TÜV Rheinland LGA Products GmbH, Tillystraße 2, 90431 Nürnberg, Deutschland.

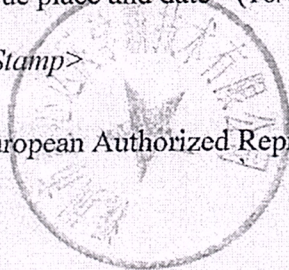
This Declaration is valid for all products concerned bearing the CE mark and manufactured by the above entitled "Manufacturer".

Shenzhen

Issue place and date (10/01/18)

<Stamp>

European Authorized Representative:



<Manufacturer's Signature>

<Name> Allen Lin

<Position> RA

Registered Address:

Obelis s.a.

Bd. Général Wahis 53

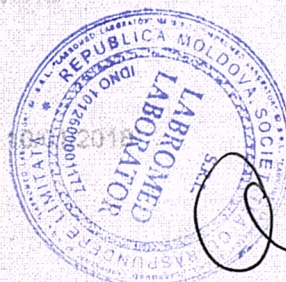
B-1030 Brussels, Belgium

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Representative: Mr. Gideon ELKAYAM (CEO)



Annex A* – List of devices

(Article 9, section 1 of the Directive 93/42/EEC on medical devices)

No.	Catalogue reference number	Commercial Name	Generic Device Term	Short description and intended use	GMDN code	Class	Rule
1		Hemostasis Valve Sets	<i>Jeluri de Ventilă</i> Hemostasis Valve Sets	Hemostasis valve set is intended to connect/introduce catheter/guide wire to facilitate the fulfillment of surgery.	36079	IIa	✓
2		Introducer Sets	<i>Introducer set</i> Introducer Sets	The introducer set is contraindicated for percutaneous introduction of guide wire or catheter into the vascular system through introducer needle.	58865	IIa	✓
3		Guide Wires	Guide Wires	The guide wire is intended for percutaneous entry of peripheral vessels. It can be used to selectively introduce and position catheters and other interventional devices within the peripheral vasculature.	35094	IIa	0
4		Connecting Tubings	Connecting Tubings	The connecting tubing is intended to provide channel for infusion and pressure monitoring, it will not contact the patient's body directly.	60538	2	2
5		Stopcocks	<i>Supapele</i> Stopcocks	Stopcock is intended to direct and control the flow of fluids.	35375	Ib	2
6		Angiographic Syringe	Angiographic Syringes	The syringe is designed for delivery of	15286	IIa	2

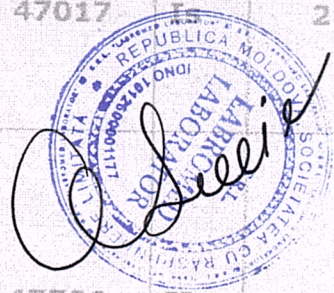


		es		contrast media with digital injector.			
7		Disposable Infusion Pumps	Disposable Infusion Pumps	Disposable infusion pumps are intended for general infusion use.	61732	IIb	3
8		Patient Controlled Analgesic Infusion Pumps	Patient-Controlled Analgesic Infusion Pumps	Patient controlled Analgesic infusion Pumps is intended for patient-controlled analgesia infusion using the integrated bolus button.	35932	IIb	3
9		Balloon Inflation Devices	Balloon Inflation Devices	The balloon inflation device is intended to use with balloon inflation catheters to create and monitor pressure in the balloon and to deflate the balloon.	17541	Is	2
10		Manifolds	Manifolds	Manifold is intended to be connected to various infusion channels to control the fluid or medication flow direction, also it is can be connected to pressure monitoring system.	47258	Is	2
11		Disposable Pressure Transducer	Disposable Pressure Transducer	The disposable pressure transducer is indicated for monitoring kinds of pressure such as central venous pressure, pulmonary artery pressure, atrial pressure to get the physiological pressure, and provide objective evidence for diagnose,	35927	IIb	10/3

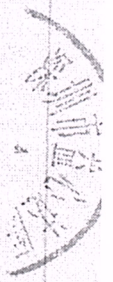
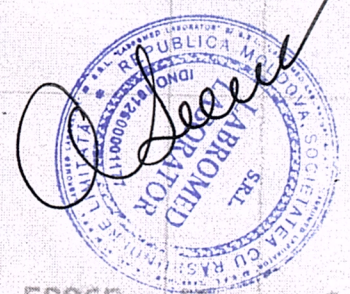


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				treatment and prognosis evaluation.			
12		Dose-control Syringes	Dose-control Syringes	Dose-control syringe is intended to facilitate manual contrast media injection during angiographic proceducer.	15286	Is	2
13	+	Hemodialysis Catheterization Kits	Hemodialysis Catheterization Kits	Hemodialysis catheter is usually placed in deep vein, like the neck (jugular vein) or chest (subclavian vein) via seldinger technique to build a temporary blood connection between the patient and the dialysis machine for acute and short-term dialysis.	60879	IIa	7
14		Colored Piston Specialty Syringes	Colored Piston Specialty Syringes	The Colored Piston Specialty Syringe is intended for injection and aspiration of high viscosity contrast media.	47017	+	2
15	+	Drainage Catheter Sets	Drainage Catheter Sets	The Drainage Catheter Set is intended for obtaining access to thoracic cavity and abdominal cavity for short-term use to externally drain fluid.	47796	IIa	7
16	?	I.V Cannulas	I.V Cannulas	IV Cannular is intended for short-term infusion of fluid from venous system.	18067	IIa	7
17		Infusion Sets with	Infusion Sets with needleless	The Infusion Set with needleless adapter is used for	42727	Is	2



		needle less adapter	adapter	drug administration for the purpose of safety, and multiple connector with the needless adapter is used for various fluid.			
18	†	Introducer Needles	Introducer Needles	The introducer needle is intended to percutaneous access of guidewire.	12747	IIa	6
19		Manifold Sets	Manifold Sets	The manifold Set is a sterile, single use surgical instrument designed to facilitate the PTCA procedure.	47258	Is	2
20	†	Percutaneous Nephrostomy Sets	Percutaneous Nephrostomy Sets	The percutaneous nephrostomy sets is used for the treatment of nephrolith.	62920	IIa	6
21	†	Tracheostomy Tube Kits	Tracheostomy Tube Kits	This tracheostomy tube kits uses the Seidinger technique to guide the specially designed guide wire dilating forceps into the trachea, which then are used to dilate the trachea.	35404	IIa	7
22	† e	Transradial Introducer Sets	Transradial Introducer Sets	The transradial introducer set is designed for the Introduction of balloon, diagnostic and guiding catheters or other devices for diagnosis and Intervention in radial artery access procedures.	58865	IIa	6
23	† p	Ureteral Stent Sets	Ureteral Stent Sets	The Ureteral Stent set is intended to facilitate the temporary internal drainage of urine from the kidney to the bladder via ureter by a trained physician.	58005	IIa	7



Manufacturer's Name

Obelis S.A.

SCW Medicath Ltd.

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Address :

Date: _____

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10/01/2018

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