Obelis SA
EUROPEAN AUTHORIZED REPRESENTATIVE CENTER

EUROPEAN RESPONSIBLE PERSON CENTER
Obelis
SINCE 1988

CERTIFICATE OF CE (MDD) NOTIFICATION

Ref. No.: HVD 5968-2017

Date: 24.11.2017

Order No.: JM 4831-2016

THIS IS TO CERTIFY THAT, ACCORDING TO THE COUNCIL DIRECTIVE 93/42/EEC WE, HERE AT OBELIS S.A. (O.E.A.R.C.) PERFORMED ALL NOTIFICATION DUTIES AND RESPONSIBILITIES AS THE EUROPEAN AUTHORIZED REPRESENTATIVE (EC REP) OF:

NAME: SITMED EQUIPAMENTOS MÉDICOS LTDA.

ADDRESS: RUA DA PAZ, 1629, BAIRRO N.SRA. APARECIDA, FLORES DA CUNHA-RS, CEP 95270-000, BRAZIL

AS STIPULATED AND DEMANDED BY THE AFOREMENTIONED DIRECTIVE.

The Manufacturer declares that the Class I * devices comply with the Directive including all essential requirements.

The Manufacturer has provided Obelis s.a. (O.E.A.R.C.) with all the appropriate declarations as per the Council Directive 93/42/EEC article 14 requirements, including the EC Declaration of Conformity (according to Annex VII) confirming that their Class I medical devices, as stipulated here below, are fulfilling the applicable requirements of the Council Directive 93/42/EEC.

The notification of the following medical devices has been completed by Obelis s.a. (O.E.A.R.C.) on the 21/11/2017 in compliance with the Council Directive 93/42/EEC - article 14 requirements.

CLASS I MEDICAL DEVICES: PLEASE SEE ANNEX A - LIST OF DEVICES (2 PAGES, 10 DEVICES)

As of the 22/11/2017, and as long as the Manufacturer will continue complying with the hereabove mentioned requirements**, he therefore:

- Is required to affix the CE marking on these devices;

- May place these devices in the European EU and EEA territory,

G.ELKAYAM CEO

Mr. G. Elkayam CEO
Obelis sa
date & stamp

OBELIS s.a. - O.E.A.R.C
Registered address :
Bd Général Wahis 53
1030 Bruxelles
Tél. +32 2 732 59 54 - Fax +32 2 732 60 03

EAAR

Obelis European Authorized Representative Center is a member of the European Association of Authorized Representatives (E.A.A.R.), ISO 9001:2008 and ISO 13485:2003 certified in accordance to the profession of a European Authorized Representative.

*also applicable to Class I s & m
** and provided that the product classification will not be rejected by the competent authorities

CE

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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	MRS 310	Essential	Ambulance stretcher, manual	Ambulance Stretcher for Medical Evacuation	35843	I	1
2	MWS 320	Level Up		Ambulance Stretcher for Medical Evacuation		I	1
3	MXS 330	Elevex		Ambulance Stretcher for Medical Evacuation		I	1
4	MCS 360	Fusion		Ambulance Stretcher for Medical Evacuation		I	1
5	MTS 410	Pegasus	Stretcher equipment mount	Evacuation Stretcher for Medical Emergencies	36178	I	1
6	MIS 100	Meduse	Spine Board	Spinal Board for Patient Immobilization	13673	I	1
7	MPS 400	Pandora III	Portable stretcher	Medical Evacuation Litter for Patients Transfer	13818	I	1
8	MPS 120	Pandora II		Medical Evacuation Litter for Patients Transfer		I	1
9	MFS 420	Krisalis		Flexible Transfer Base for Emergency Evacuation		I	1
10	MCS 200	Ágila	Transport Wheelchair, colapsible	Evacuation Stair Chair for Medical Emergencies	45052	I	1

* Annex A is part of the Agreement.

** The here above product list classification is based on the classification claim of the manufacturer and under its sole responsibility (MDD 93/42/EEC, article 2 & Annex IX; MEDDEV 2.4/1 Rev.9, chapter 3.1 & 3.3)

G.ELKAYAM C.E.O

Sitmed Equip Med Ltda	Obelis S.A.
Signature:	Signature: G.ELKAYAM C.E.O.
Date: 30/10/2017	Date: 28/11/2017
Stamp:	Stamp:

02 473 977/0001-51
SITMED EQUIPAMENTOS MÉDICOS LTDA.
Rua Da Paz, 1629
BAIRRO CENTRO
CEP 95270-000
FLORES DA CUNHA - RS

OBELIS s.a. - O.E.A.R.C
Registered address :
Bd Général Wahis 53
1030 Bruxelles
Tél. +32 2 732 59 54 - Fax +32 2 732 60 03