Obelis SA
EUROPEAN AUTHORIZED REPRESENTATIVE CENTER

EUROPEAN RESPONSIBLE PERSON CENTER
Obelis SA
SINCE 1988

CERTIFICATE OF CE (MDD) NOTIFICATION

Ref. No.:AF 3568-2014

Date: 15/12/2014

Order No.: CH 2406-2013

THIS IS TO CERTIFY THAT, ACCORDING TO THE EUROPEAN 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: SPOL CO., LTD.

ADDRESS: 405, WORLDMERIDIAN-BIZ CENTER YANGPYEONG-DONG 3-GA YEONGDEUNGPO-GU, SEOUL, KOREA

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 European Council Directive 93/42/EEC article 14 requirements, including the EC Declaration of Conformity (according to Annex VII) confirming that their Class I medical device, as stipulated here below, is fulfilling the applicable requirements of the European Council Directive 93/42/EEC.

The notification of the following medical device has been completed by Obelis s.a. (O.E.A.R.C.) on the 20/11/2014 in compliance with the European Council Directive 93/42/EEC - article 14 requirements.

CLASS I MEDICAL DEVICES: PLEASE SEE ANNEX A - LIST OF DEVICES (1 PAGE, 1 DEVICE)

As of the 21/11/2014, and as long as the Manufacturer will continue complying with the hereabove mentioned requirements**, he therefore:

- Is required to affix the CE marking on this device;

- May place this device in the European community territory,

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

G. ELKAYAM

Mr. G. Elkayam CEO
Obelis sa
date & stamp

SEEN
by the Brussels Chamber of Commerce
Evelien Jonckheere
Brussels, the 18 DEC. 2014

Brussels Enterprise
Commerce & Industry
date & stamp

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

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CE