Annex A* – List of devices

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

No.	Generic Device Term	Commercial name	Class**	Rule	Catalogue reference number	Short description and intended use	GMDN code***
1	Skin-cover adhesive strip	EU Halo Seal	I	4	n/a	Non-resorbable and non-sterile occlusive wound dressing intended to cover a wound used as a mechanical barrier.	44990

* 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 7 & Annex IX, MEDDEV 2.4/1 Rev.9, chapter 3.1 & 3.3)
*** GMDN codes are mandatory information to perform the Notification

Manufacturer's Name	Obelis S.A.	BECI
Signature:	Signature:	Signature:
Date: 12/1/14	Date: 16/2/2015	Date:
Stamp:	Stamp:	Stamp:

EUROPEAN AUTHORIZED REPRESENTATIVE CENTER
SINCE 1988
obelis SA
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

CHAMBRE DE COMMERCE ET D'INDUSTRIE DE BRUXELLES
17-02-2015

Obelis SA
EUROPEAN AUTHORIZED REPRESENTATIVE CENTER

EUROPEAN RESPONSIBLE PERSON CENTER – Obelis – SINCE 1988

CERTIFICATE OF CE (MDD) NOTIFICATION

Ref. No.: JW3678-2015

Date: 20/01/2015

Order No.: JW3512-2014

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: HEART SYNC INC.

ADDRESS: 5643 PLYMOUTH ROAD, ANN ARBOR, MICHIGAN 48105, USA

AS STIPULATED AND DEMANDED BY THE AFOREMENTIONED DIRECTIVE.

The Manufacturer declares that the Class I * device complies 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/are 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 19/01/2015 in compliance with the European Council Directive 93/42/EEC - article 14 requirements.

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

As of the 20/01/2015, and as long as the Manufacturer will continue complying with the here above 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 :
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1030 Bruxelles
Tél. +32 2 732 59 54 - Fax +32 2 732 60 03

Mr. G. Elkayam CEO
Obelis sa
date & stamp

SEEN
by the Brussels Chamber of Commerce
Evelien Jonckheere

Brussels, the 17 FEV. 2015

Brussels Enterprise
Commerce & Industry
date & stamp

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