

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	Powder Free Examination Glove	EMG	1	5	EMNE 80300 Series	A Powder Free Nitrile Examination glove is a disposable device made of synthetic polymer that would not contain of any protein trace and is intended to be worn on the hand finger(s) for medical purpose to provide a barrier against potentially infectious material and other contaminants	UMDNS 11882

* 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)

*** GMDN codes are mandatory information to perform the Notification

Manufacturer's Name

Obelis S.A.

ECO Medi Glove Sdn Bhd

Cheong Kin Fy
 Cheong Kin Fy

Signature: _____

Signature: _____

24/2/2015

Date: 09/07/2015

Date: _____

Stamp: S. FERRETTI C.C.O.

Stamp: _____

ECO MEDI GLOVE SDN. BHD.
 (Co. Reg. No. 815262-D)
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