

CERTIFICATE

OF

MDD NOTIFICATION



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Obelis European Authorized Representative Center is a member of the European Association of Authorized Representatives (E.A.A.R.), ISO 9001 : 2015 and ISO 13485 : 2016 certified in accordance to the profession of a European Authorized Representative.

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	Laryngoscope	Laryngoscope Standard Sololite	I	5	810-201-00 to 810-201-05 810-211-00 to 810-211-05 810-221-00 to 810-221-04 810-231-02 to 810-231-04 810-241-02 to 810-241-04 810-261-01, 810-251-03 810-271-01 to 810-271-02 810-281-00 to 810-281-01 810-291-00 to 810-291-01 810-301-02 to 810-301-04 810-500-25 to 810-504-25	To visualize and examine the upper airway of a patient and to guide placement of the endotracheal tube during intubation procedure.	15076
		Laryngoscope F.O Lunalite			810-011-00 to 810-011-05 810-021-00 to 810-021-05 810-031-00 to 810-031-05 810-041-00 to 810-041-04 810-051-00 to 810-051-04 810-061-02 to 810-061-04 810-081-01, 810-071-03 810-091-01 to 810-091-02 810-100-00 to 810-100-01 810-110-00 to 810-110-01 810-120-02 to 810-120-04 810-530-25 to 810-533-35 810-560-25 to 810-563-35 810-451-25 to 810-455-25		
		Laryngoscope F.O Maxlite			810-001-00 to 810-001-05 810-130-02 to 810-130-04		
	Laryngoscope (Single Use)	Lunalite 'D'®			810-401-00 to 810-401-04 810-411-00 to 810-411-05 810-421-00 to 810-421-01 810-431-01 810-481-03 to 810-481-04 810-441-01 to 810-441-04 810-461-00 to 810-461-05 810-455-25, 810-457-25 810-459-25, 810-475-25 810-471-25, 810-473-25	To visualize and examine the upper airway of a patient	46828
2	Otoscope Set	Otoscope Set Standard Omni	I	5	808-450-01, 808-452-01	For Examination of Ear, Nose and Throat	12849
		Otoscope Set F.O Visio			808-600-25, 808-601-35 to 808-603-35		
		Otoscope Set Standard Mark-I			808-990-25		
		Otoscope Set Standard Mark-II			808-800-25 to 808-832-35		
3	Ophthalmoscope	Ophthalmoscope Standard Omni	I	5	808-454-01, 808-456-01	For Examination of Eye	46786
		Ophthalmoscope Standard Visio			808-605-25, 808-606-35 to 808-608-35		
		Ophthalmoscope Standard Optek			808-992-25, 808-808-25 to 808-840-35		
4	Dermatoscope	Dermatoscope Standard Sigma	I	12	808-550-25	For Examination of Skin	18021
		Dermatoscope Standard Omni			808-560-25		
5	F.O. Light Cables	F.O. Light Cables Standard	I	12	830-301-18 to 830-346-30	For Light Transmission	35507
		F.O. Light Cables Xenon			830-351-18 to 830-396-30		
6	Clar Headlight	Clar Headlight MD- 100	I	12	808-700-04 to 808-700-09	Light Source for ENT Surgery	34637
		Clar Headlight MD-			808-702-06, 808-714-06		

	F.O Headlight	110			808-704-04 808-704-06 808-716-04-808-716-06		46808
		Clar Headlight MD-120			808-746-01		
		F.O Headlight MD730			808-750-01		
		F.O Headlight MD750			808-752-01		
		F.O Headlight MD751					
8	Proctology Instrument	Proctology Instruments Sigmoidoscope	I	5	819-090-21, 819-092-21 819-94-01, 819-096-01, 819-098-01, 819-088-30	For Examination of Rectum	15058
		Proctology Instruments Anoscope			819-080-01, 819-082-01, 819-084-01, 819-190-16, 819-192-19, 819-194-22, 819-212-30, 819-220-19, 819-222-22		10156
		Proctoscope			819-170-21, 819-172-27, 819-180-02, 819-182-04, 819-184-06, 819-186-08, 819-112-17, 819-114-21, 819-116-24, 819-118-17, 819-120-21, 819-122-24, 819-124-17, 819-126-21, 819-128-24, 819-130-17, 819-132-21, 819-134-24		35255
9	Percussion Hammers	Percussion Hammers (Taylor)	I	1	808-970-17, 808-972-20	To Check the Reflexes of patient	11950
		Percussion Hammers (Dejrine)			808-978-01, 808-980-21		
		Percussion Hammers (Babinsky)			808-976-22		
		Percussion Hammers (Buck)			808-984-15, 808-986-18		
10	Battery Charger	Battery Charger Zoom	I	1	808-053-00, 808-054-00 808-053-01, 808-053-02 808-531-03	To Charge Rechargeable Battery	17115

* 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

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