

Il Fabbricante / The Manufacturer / Le Fabricant / Vom Herstellers / El fabricante:

FARO S.p.A.
Via Faro 15, 20876 - Ornago (MB) - Italy
SNR: IT-MF-000029670
www.faro.it

IT - dichiara sotto la sola propria responsabilità, che il dispositivo:
EN - declares under its own responsibility, that the device:
FR - déclare sous sa propre responsabilité, que les dispositifs :
DE - erklärt auf eigene Verantwortung, dass Gerät:
ES - declara bajo su propia responsabilidad que el dispositivo:

Trade Name	GMDN code	REF (Models)	Basic UDI-DI	Annex VIII - MDR	
				Rule	Class
B75	12282 Operating room light	Annex 1	805432051B75BE	10	I

IT - in tutte le sue varianti, soddisfa i requisiti del Regolamento (UE) 2017 /745
EN - in all its versions, meets the Requirements laid down in Regulation (EU) 2017/745.
FR - dans ses différentes versions, satisfait les Exigences des Règlement (UE) 2017/745.
DE - in all seinen Varianten, erfüllt die Anforderungen von der Verordnung (EU) 2017/745
ES - en todas sus versiones, cumpla los Requisitos establecidos en el Reglamento (UE) 2017/745

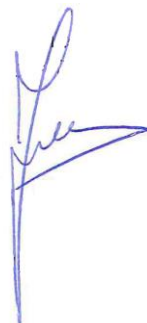
IT - Per la valutazione della conformità sono state applicate le seguenti norme:
EN - The following standards were used for the conformity assessment:
FR - Les normes suivantes ont été utilisées pour l'évaluation de la conformité:
DE - Die folgenden Normen wurden für die Konformitätsbewertung angewendet:
ES - Las siguientes normas se han utilizado para la evaluación de la conformidad:

IEC/EN 60601-1
IEC EN 60601-2-41
IEC/EN 80601-2-60
IEC/EN 60601-1-2
IEC/EN 62366
IEC/EN 60601-1-6
IEC/EN 62471
ISO/EN 9680

Common Standard Specification: N/A

Ornago: 06/11/2024
Dr. Angelo Favonio

Amministratore Delegato



Annex 1 - List of Codes

Type	M	C	T	L	F	CC
55	U	0	0	0	X	JJ
	C	1	1	1		
	T			2		
	S			3		

REF is composed by 9 digits: 55MCTLFCC

- 55: fixed prefix of two digit to identify the Type of the device: B75
M: one digit. Identifies the type of mounting: Dental Unit Mounting includes also Floor Mounting and Wall Mounting
C: one digit. Identifies the presence of the integrated Camera.

- T: one digit. Identifies the presence of the Theia secondary light source on the fixed arm.
L: one digit. Identifies the Length of the fixed arm
F: one digit. Available for internal changes.
CC: two digits. Identifies any customization of any minor feature of the device.