

ESAOTE S.p.A.– List of CE marked products under MDR

Category	EMDN Code	Basic UDI-DI	Article / model number	Article / models name	Class	Rule	GMDN code	UMDNS code	MD Group	MDA Code	MDS	MDT Code	CE Certificate	Expiration date
Multifunctional ultrasound scanner	Z110401	805630445ESA.US0000001.XT	6440	MyLab 9 eXP; MyLab 9; MyLabX9; MyLabX9 Pro; MyLabX90; MyLabX90 eXP; MyLabX90 eHD; MyLabX90 Pro; MyLabX95; MyLabX90; MyLabX90 elite; MyLabX90 Pro; MyLabX90 Plus;	IIa	10	40761	14278	MD 1202_1	0202	1009	2010	G10 095545 0024	2026 Aug-24
		805630445ESA.US0000007.YD	6430	MyLabX75; MyLabX75 eHD; MyLabX75 eXP; MyLab XPro75; AC750;								2011		
		805630445ESA.US0000004.Y4	6450	MyLabX8; MyLabX8 eXP; MyLab XPro80; MyLabX8 elite; MyLabX8 Pro; MyLabX8 eHD; MyLabE8; MyLabE8 eXP; MyLab880;								2012		
		805630445ESA.US0000002.XW	6420	MyLabX5;										
		805630445ESA.US0000003.XZ	6400	MyLabX6; MyLabX7; AC600;										
		805630445ESA.US0000005.Y7	7400	MyLab XPro30; MyLabOmega; MyLabOmega eXP; MyLab250 XV; MyLab300 XV										
		805630445ESA.US0000006.YA	7410	MyLabSigma; MyLabSigma elite; AL300;										
		805630445ESA.US0000008.YG	66XX	MyLabA; MyLabA50; MyLabA60; MyLabA70; MyLabA500 AI; MyLabA650 AI; MyLabA750 AI;										
Probes for ultrasonic medical diagnostic systems	Z110402	805630445ESA.PR0000001.SK	Convex Low Freq.	C 1-8; CX 1-8; AC2541; SI2C41; C 1-8E	IIa	10	40768	16272	MD 1202_1	0202	n.a.	2010		
		805630445ESA.PR0000002.SN	Convex High Freq.	C 2-9;								2011		
		805630445ESA.PR0000011.SQ	Phased Array	P 1-5; 2CWS; 5CWS; PX 1-5; 2CWL; 5CWL; SP2730; P 1-5E										
		805630445ESA.PR0000008.T8	Linear Low Freq.	L 3-11;										
		805630445ESA.PR0000009.TB	Linear Med. Freq.	LMX 3-15; LX 3-15; L 4-15; L 3-15E										
		805630445ESA.PR0000010.SM	Linear High Freq.	LMX 4-20; IHX 6-25; SL3235; SL3116; SL2325; L 8-24;										
		805630445ESA.PR0000015.T4	Volumetric	SB2C41;										
		805630445ESA.PR0000003.SR	Convex 10 - 20mm	mC 3-11;										
		805630445ESA.PR0000012.ST	Phased Med. Freq.	P2 3-11; P 2-9;										
		805630445ESA.PR0000013.SW	Phased High Freq.	P2 5-13;										
		805630445ESA.PR0000014.SZ	Trans-esophageal	TE 3-8;			37891							
		805630445ESA.PR0000005.SX	Endocavity	E 3-12; SE3133;			40771							
Magnetic resonance imaging units for medical diagnosis	Z110501	805630445ESA.MR0000002.PX	100009	Magnifico Open	IIa	10	37652	18108	MD 1202_2	0202	1009	2010		
		805630445ESA.MR0000004.Q5	100001	S-scan Open								2011		
	Z11050101	805630445ESA.MR0000001.PU	100009	Magnifico MSK			37651	18109				2012		
		805630445ESA.MR0000003.Q2	100001	S-scan MSK										
Software for diagnostic imaging	Z11069092	805630445ESA.SW0000001.YV	100210	MyLabDesk	IIa	11	40943	17960	1111	0315	1010	2010		

All the products are not sterile and not OEM.

Revision history

Rev.01	August, 24, 2021	First emission
Rev.02	September, 27, 2021	Category correction to EMDN definition
Rev.03	November, 29, 2021	Adding of MD Group classification and devices Magnifico Open, Magnifico MSK, 6430 family, 2CWS and 5CWS probes
Rev.04	May 17, 2022	Adding of probes CX 1-8 and LMX 3-15
Rev.05	June 17, 2022	Adding of probe LMX 4-20
Rev.06	July 11, 2022	Adding of probes LX 3-15 and TE 3-8
Rev.07	September, 30, 2022	Modified GMDN code for probe TE 3-8 and adding of the following devices: MyLab 9; MyLabX9; MyLabX9 Pro; MyLabX8; MyLabX8 eXP; MyLab XPro80; MylabX8 elite; MylabX8 Pro; MyLabX8 eHD; MyLabX6; MyLabX7; MyLabX5; MyLab XPro30; MyLabOmega; MyLabSigma; MyLabSigma elite; AC2541; C 2-9; L 4-15; PX 1-5
Rev.08	November, 17, 2022	Adding of the following devices: MyLabX90; MyLabE8; MyLabE8 eXP; MyLab880; 2CWL; 5CWL
Rev.09	February, 28, 2023	Adding of the following devices: MyLabOmega eXP; MyLab250 XV; MyLab300 XV; MyLabX90 eXP; MyLabX90 eHD; MyLabX90 Pro; MyLabX95; MyLabX90; MyLabX90 elite; MyLabX90 Pro; MyLabX90 Plus.
Rev.10	April, 17, 2023	Added probe E 3-12 after receiving final ok from TUV of CN 03 2022
Rev.11	June, 08, 2023	Adding of the following devices: AC750; AC600; AL300
Rev.12	July, 11, 2023	Adding of the following devices: MyLabDesk after receiving final ok from TUV - CN 05 2022
Rev.13	July 18, 2023	Adding of the following devices: S-scan Open and S-scan MSK - CN 05 2023
Rev.14	September 13, 2023	Adding of the following device: IHX 6-25
Rev.15	October 12, 2023	Adding of the following devices: SI2C41; SP2730; SL3235; L3116; SL2325; L 8-24; SB2C41; mC 3-11; P2 3-11; P 2-9; P2 5-13; SE3133; C 1-8E; P 1-5E; L 3-15E October 10, 2023
Rev.16	October 27, 2023	Adding of the following devices: MyLabA; MyLabA50; MyLabA60; MyLabA70; MyLabA500 AI; MyLabA650 AI; MyLabA750 AI;