7. EUPseries

		EUP-B514	EUP-L53L	EUP-O54J	EUP-B715	EUP-C715
Manufacturer		FUJIFILM Healthcare Corporation	FUJIFILM Healthcare Corporation	FUJIFILM Healthcare Corporation	FUJIFILM Healthcare Corporation	FUJIFILM Healthcare Corporation
Type of probe (convex, linear, endocavitary,sector, 3D, 4D...)		convex	linear	linear	convex	convex
Number of elements		192	256	128	160	160
Nature of elements *1 crystals, ceramics, polymers, composite, CMUT		ceramics	ceramics	ceramics	ceramics (multi-layer)	ceramics (multi-layer)
Shape of elements		40R	-	-	50R	50R
Dimension of the skin contact area (mm x mm)		79.8 × 14.8	99.4 × 11	5.5 × 28.7	72.8 x 15	72.8 x 15
Field of view (linear: width, convex: sector angle)		C: 90deg.	L: 92mm	L: 25mm	C: 70deg.	C: 70deg.
Type of scanning: mechanical? Electronic linear? Sector electronics (phased array or curved probe)?		Electronic convex	Electronic linear	Electronic linear	Electronic convex	Electronic convex
For 3D / 4D probes: rotation of the probe (electronic or mechanical)		N/A	N/A	N/A	N/A	N/A
For 3D / 4D probes: sweep angle (in degrees)		N/A	N/A	N/A	N/A	N/A
Nominal Imaging Frequencies		3.5MHz (5-2MHz)	7.5MHz (10-5MHz)	10.0MHz (13-7MHz)	3.5MHz (5-1MHz)	3.0MHz (5-1MHz)
Weight (probe + connection cable)		390	1040	190	320	320
Cable length (cm)		220	220	220	220	220
Fully immersible probe *2		X	N/A	X	N/A	N/A
Sterilization is possible		X	X	X	X	X
Recommended method for decontamination and recommended products (Trade name versus active ingredient)		See Instructon Manual	See Instructon Manual	See Instructon Manual	See Instructon Manual	See Instructon Manual
	Reference	Q1E-EP0616	Q1E-EP0348	Q1E-EP1064	Q1E-EP1245	Q1E-EP1011
Recommended method for disinfection and recommended products (Trade name versus active ingredient)		See Instructon Manual	See Instructon Manual	See Instructon Manual	See Instructon Manual	See Instructon Manual
	Reference	Q1E-EP0616	Q1E-EP0348	Q1E-EP1064	Q1E-EP1245	Q1E-EP1011
Biopsy guide		X	N/A	N/A	X	X

*1 Suppose "composite" means 2 dimensional cut structure, All coorresponding natures of each probe are stated.

*2 When immersing, optional waterproof box "EZU-WB1-H" is necessary. The resistance to water pressure resistance is up to 20 kPa.

EU Certificate

Quality Management System
REGULATION (EU) 2017/745 on Medical Devices, Annex IX Chapter I, Section 2 and 3 and Chapter III

TÜVRheinland®

Registration No.:	HZ 2251444-2
Manufacturer:	**FUJIFILM Healthcare Corporation** 2-1, Shintoyofuta, Kashiwa-shi, Chiba 277-0804 Japan
EUDAMED Single Registration No.:	JP-MF-000018708
Products:	Products of class IIa: Z110401 - ULTRASOUND SCANNERS Z110402 - ULTRASOUND PROBES
Authorised representative(s):	FUJIFILM Healthcare Deutschland GmbH Otto-von-Guericke-Ring 3, D-65205 Wiesbaden, Germany

Certificate history		
Revision:	Description:	Issue date:
1	Initial issue	2022-04-01
2	Added product (Z110402)	2022-10-24

The Notified Body hereby declares that the requirements of Annex IX, Chapter I, Section 2 and 3 of the REGULATION (EU) 2017/745 have been met for the listed products. The above named manufacturer has established and applies a quality management system, which is subject to periodic surveillance, defined by Annex IX, Chapter I, Section 3 of the aforementioned regulation. The requirements of Annex IX, Chapter III are fulfilled. If class III devices or class IIb implantable devices referred to in the second subparagraph of Article 52(4) are covered by this certificate an EU technical documentation assessment certificate according to Chapter II, Section 4.9 is required before placing them on the market.

Report No.:	150243855-357
Effective date:	2022-10-24
Expiry date:	2026-10-01
Issue date:	2022-10-24

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle TÜVRheinland®

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
BS-MDR-091

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TÜV Rheinland LGA Products GmbH is a Notified Body according to REGULATION (EU) 2017/745 concerning medical devices with the identification number 0197.