

FUJIFILM Healthcare Italia S.p.A.

MEDICAL DEVICE SOFTWARE MANUFACTURER

MEDICAL DEVICE

SYNAPSE VALUE

Release 2.x.x.x

SYNAPSE[®]
value

IHE INTEGRATION STATEMENT

Rev.05 – 01/09/2025





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Partita IVA: IT11025740157

Rea: MI-1292685

EUDAMED ID/SRN: IT-MF-000029974



Medical Devices Regulation (EU) 2017/745: **Class IIa**

EN 62304: **B**

European Medical Device Nomenclature (EMDN)/Classificazione Nazionale Dispositivi medici (CND): **Z119092**

- STRUMENTAZIONE VARIA PER BIOIMMAGINI E RADIOTERAPIA – DISPOSITIVI MEDICI SOFTWARE

BASIC UDI: **805699280SYNAPSEVALUEKQ**

UDI-DI: **08056992800014**

UDI-DI: **08056992800038**

Paesi dell'UE in cui si intende commercializzare il dispositivo medico:

- **Italia.**

DOCUMENT FILE NAME / NOME DEL FILE DEL DOCUMENTO

DOCUMENT REVISION HISTORY / CRONOLOGIA DI REVISIONE DEL DOCUMENTO

REVISION / REVISIONE	DATE / DATA	CHANGE / MODIFICHE	NOTES / NOTE
Rev.05	01/09/2025	Modifica sede legale	
Rev.04	24/06/2024	Cambio nome documento	
Rev.03	29/04/2024	Cambio denominazione società	
Rev.02	26/06/2023	Modifiche Segnalazioni MDR (EU) 2017/745	
Rev.01	07/02/2023		SYNAPSE VALUE 2.0.x
Rev.00	03/10/2022		SYNAPSE VALUE 1.6

DOCUMENT CONFIDENTIALITY / RISERVATEZZA DEL DOCUMENTO

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IHE Integration Statement			
Vendor	Product Name	Date	Version
FUJIFILM Healthcare Italia S.p.A.	SYNAPSE Value	01/09/2025	2.x.x.x
This product implements all transactions required in the IHE Technical Framework to support the IHE profiles, actors and options listed below.			
Integration Profiles Implemented	Actors Implemented	Options Implemented	
Scheduled Workflow.b	DSS/Order Filler	Availability of PPS-Referenced Instances	
		Image Availability Query	
Patient Information Reconciliation	DSS/Order Filler	None	
Reporting Workflow	DSS/Order Filler	None	
Import Reconciliation Workflow	DSS/Order Filler	None	
	Performed Procedure Step Manager	None	
Cross Enterprise Document Sharing	Document Source	None	
	Document Consumer	None	
Consistent Time	Time Client	None	
Post Processing Workflow	DSS/Order Filler	None	
	Post-Processing Manager	None	
Mammography Acquisition Workflow	DSS/Order Filler	None	
	Performed Procedure Step Manager	None	
Radiation Exposure Monitoring REM	Dose Register	None	
	Dose Info Reporter	None	
	Dose Info Consumer	None	
Internet address for vendor's IHE information: https://www.fujifilm.com/it/it/about/us/offices/fujifilm-italia-unita-operativa-locale-di-bolzano			
Links to Standards Conformance Statements for the Implementation			
HL7	https://www.fujifilm.com/it/it/about/us/offices/fujifilm-italia-unita-operativa-locale-di-bolzano		
DICOM	https://www.fujifilm.com/it/it/about/us/offices/fujifilm-italia-unita-operativa-locale-di-bolzano		
Links to general information about IHE worldwide: http://ihe.net/IHE_Worldwide			



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Subject to direction and coordination of FUJIFILM Europe B.V. (Netherlands) Sole Shareholder

Capitale Sociale € 2.580.000 i.v. - Reg. Imprese MI 1292685 - Codice Fiscale 09435590154 - P.IVA IT 11025740157

Soggetta all'attività di direzione e coordinamento di FUJIFILM Europe B.V. (Paesi Bassi) Socio Unico

