

Starviewer
Medical Imaging Software

EU Declaration of Conformity

Record

Manufacturer	Address
Institut de Diagnòstic per la Imatge SRN: ES-MF-000004605	Parc Sanitari Pere Virgili Edifici Mestral, 2a planta Carrer d'Esteve Terradas, 30 08023 Barcelona

DECLARE UNDER THEIR SOLE RESPONSIBILITY THAT THE MANUFACTURED PRODUCT

Basic UDI-DI	84370252524PDH7JQ67
EMDN code	Z11030592 – Radiology instruments – Medical device software
Intended use	Starviewer is a medical software platform intended to provide support for diagnosis and clinical decision from medical images by healthcare professionals. It is an application for the visualisation and processing of medical images stored in DICOM (Digital Imaging and Communications in Medicine) format.
Classification	Ila (Annex VIII Rule 11)

CONFORMS WITH THE GENERAL SAFETY AND PERFORMANCE REQUIREMENTS AND PROVISIONS OF THE REGULATION:

Regulation (EU) 2017/745	Medical Devices Regulation
Conformity assessment route:	Annex IX
Technical documentation:	gms://doc/technicalDocumentation – Nº2165
Notified Body:	BSI – NB 2797 BSI Group The Netherlands B.V. Say Building John M. Keynesplein 9 1066 EP Amsterdam +31 (0)20 3460780 Certificate number MDR 782858 valid until 2030-05-28
Specific harmonised standards:	EN ISO 14971:2019+A11:2021
Quality system according to:	EN ISO 13485:2016+A11:2021

This declaration is valid only together with the device release records according to the applicable quality system.

Barcelona, 2025-06-04

Technical Manager	Assistant Manager
Mario Rabasseda Hurtado	Virginia Benavente Ballesteros
	On behalf of General Manager Francesc Garcia Cuyàs
	