



Declaration of Conformity

Record

Manufacturer

Institut de Diagnòstic per la Imatge

AddressParc Sanitari Pare Virgili
Edifici Mestral, 2a planta
C./Esteve Tarrades, 30
08023 Barcelona

DECLARE UNDER THEIR SOLE RESPONSIBILITY THAT THE MANUFACTURED PRODUCT**GMDN code**

57812 – Radiology DICOM image processing application software

Intended UseStarviewer 1.1.0 is an application for the visualization and processing of
DICOM medical images**Classification**

IIa (Annex IX Rule 10)

1. CONFORMS WITH THE ESSENTIAL REQUIREMENTS AND PROVISIONS OF THE DIRECTIVES:

EC Dir. 93/42/EEC

Medical Devices Directive,

as amended

Medical Devices Directive, as transposed into national laws

Conformity assessment route

Annex II excluding section 4

Technical documentation:

<qms://doc/technicalDocumentation> – Nº2024

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 CE 708330 valid until 2024-05-26

Specific Harmonized standards:

EN 62304:2006+A1:2015 and EN ISO 14971:2019

Quality System according to:

EN ISO 13485:2016+AC:2018

2. It can be legally manufactured and placed on the market by the manufacturer, without significant changes in the design and the intended purpose according to MDR art. 120.3 until the end of validity of the certificate and maximum until May 26, 2024.

3. Also, in accordance with art. 120.4 of the MDR, may continue to be placed on the market or put into service by importers and distributors until May 26, 2025.

This declaration is valid only together with the device release records according to the applicable Quality System.

Technical Manager

Mario Rabasseda Hurtado

Assistant Manager

Virginia Benavente Ballesteros