FUJIFILM
Value from Innovation

EC Declaration of Conformity

We, the undersigned manufacturer

FUJIFILM Europe GmbH – Sucursal em Portugal
Ed. Tower Plaza, Rotunda Eng. Edgar Cardoso, 23 10°
4400-676 Vila Nova de Gaia
PORTUGAL

Herewith declare under our sole responsibility that the product here below:

***Product/ model*:**	**Synapse CWM Suite**
Product /description:	Synapse CWM Suite is a medical device software that provides the integration between picture archiving and communication system (PACS) and the management of the clinical workflow. This solution also allows the study visualization and operates the imaging processing of these studies.
MDD Classification (MDD):	**I** (*Annex IX, rule 12*)

meet the provisions of the following EC Directives, Regulations and Standards:

Medical Device Directive:	*93/42/EC Directive as amended by 47/2007/EC Directive* (*Conformity Assessment Procedure Annex VII*)
Harmonized Standards applied:	EN 62304:2006 + AC:2008 EN 62366:2008 EN ISO 14971:2012 EN ISO 15223-1:2016 EN 1041:2008

FUJIFILM Europe GmbH – Sucursal em Portugal maintains a certified quality management system according the EN ISO 13485:2016 standard (Certificate no.: 39 05 0121801)

Vila Nova de Gaia,
2021-05-03

FUJIFILM Europe GmbH – Sucursal em Portugal
Legal Representative