

EC Declaration of Conformity

Manufacturers Name: Kanteron Systems S.L.U.

Manufacturers Address: Catedrático Agustín Escardino 9, PCUV
46980 Paterna – Valencia (Spain)

SRN (Single Registration Number): 7506-PS

Name of the Device (s): Software Para Almacenamiento y Visualización de Imagen e Información Médica (*Medical Device Data System - Medical Image Storage and Communications Device*).

Product code: Kanteron Systems Precision Medicine Platform
Kanteron TMIS
Kanteron PACS-RIS-VNA
Digital Pathology Kanteron Systems
Genomics-Pharmacogenomics Kanteron Systems

Classification: Class I

Conformity assessment route: Kanteron Systems S.L.U. uses the following procedures for the CE-labeling of their products:


Class I: EC conformity declaration according to *Real Decreto 1591/2009, 16 de octubre, por el que se regulan los productos sanitarios*

This declaration of conformity is issued under the sole responsibility of Kanteron Systems S.L.U.

We hereby declare that the medical device(s) specified above meet the provision of the “Real Decreto 1591/2009, 16 de octubre, por el que se regulan los productos sanitarios.”

All supporting documentation is retained at the premises of the manufacturer.

Signature:



Jorge Cortell
CEO

Place and date (dd.mm.yyyy) of issue:

Valencia, Spain: 11/02/2020