PIXEL technology

Declaration of EC Conformance

We, Members of the Board of Pixel Technology Ltd in Lodz, 1 Piękna Street, state that:

Medical Integrated System AlleRad
in modules: ExPACS, Exhibeon. EXP, Chazon, Robo, RadiBox

Is conformant with requirements of 93/42/EC Directive for medical devices in IIb class (rule no 10), Act on Medical Devices (i.e. Journal of Laws 2010, No. 107, item 679), combined with executive acts and for this type of IIb class device procedures indicated in Annex II (except form point 4) have been applied, in order to mark with CE label.

Reference documents (harmonised norms)

• PN-EN ISO 13485:2012	Medical devices -- Quality management systems
• PN-EN ISO 14971:2012	Medical devices. Application of risk management to medical devices
• PN-EN 62304:2010	Medical Device Software - Software Life-Cycle Processes
• PN-EN 62366:2008	Medical Devices - Application Of Usability Engineering To Medical Devices
• PN-EN 1041+A1:2013-12	Information supplied by the manufacturer of medical devices

Additional reference documents

• HL7 Messaging Standard Version 2	Standard of electronic exchange of information in medical environments
• The DICOM Standard 2015c	Standard of exchange and interpretation of medical data representing or associated with diagnostic images in medicine
• PN-EN ISO 15223-1:2012	Medical devices -- Symbols to be used with medical device labels, labelling and information to be supplied -- Part 1: General requirements

Characteristics of the device

Medical Integrated System AlleRad is a software to be used in individuals to diagnose run of disease, effects of injuries or handicap as well as to examine anatomical structure or physiological processes. It allows for registration, storing, sharing, sending and exchange of data between medical systems in DICOM 3.0, HL7 standards. It allows displaying of radiology studies and discloses set of mechanisms and tools enabling making diagnosis.

Code and generic name according to UMDNS	26-869 Picture Archiving and Communication System Information System Software
Number of EC certificate of conformance	EC Certificate WE No. 1434-Md-99/2017
Name, address and identification number of a notified body	Polskie Centrum Badań i Certyfikacji Ul. Kłobucka 23A 02-699 Warszawa Notified body no 1434

We declare with full responsibility that medical device fulfills requirements indicated in the aforementioned reference documents on the condition of its use in accordance with destiny, binding norms and technical recommendations.

Jakub Musiałek

Adam Szczepanik

Łódź, 22.12.2017