



EC DECLARATION OF CONFORMITY

Producer	MEDORO s.r.o., Hraniční 10, 530 03 Pardubice, IČ: 26002612
Product	Dicompass Recorder
Intended use	obtaining data from external audio / video sources and storing them in DICOM format
Classification	Class I

The manufacturer declares that this product fulfills the requirements of the Act no. 268/2014 Coll. on medical devices and is safe with the purpose of use under normal conditions. The manufacturer has adopted measures to ensure conformity of other products with the technical documentation pursuant to Annex no. 7 of Decree no. 54/2015 Coll., stored at the manufacturer and according to the basic requirements in accordance with Annex no. 1 of the same Government Regulation.

In the design, development and manufacturing of producer take into account the requirements of the applicable technical standards relating to product:

ČSN EN 60601-1 ed.2:2007

ČSN EN 60601-1-2 ed.2:2008

ČSN EN 62304:2007

ČSN EN 14971:2012

ČSN EN ISO 10993-1

ČSN EN ISO 15223-1

Electromagnetic compatibility requirements were examined in the test laboratory of the Engineering Test Institute in Brno, Hudets 56b, 00 621 with subsequent issuance of the certificate:

Number of certificate	B-32-00431-16
Date of publication	20.4.2016
Released on the basis of final report	č. 32-0274 ze dne 20.4.2016

June 28, 2016 in Pardubice

Ondřej Koloničný
CEO