EU Declaration of Conformity

acc. to Regulation (EU) 2017/745, Annex IV

We, the manufacturer

IMAGE Information Systems Europe GmbH
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declare, under our sole responsibility, the conformity of the medical device specified below with all applicable requirements of the Medical Device Regulation (MDR) 2017/745.

Device/trade name(s)	**iQ-SYSTEM PACS**		
Device version	**v1**		
Basic UDI-DI	++B403IQSYSTEMPACS1YG		
Intended purpose	A picture archiving and communication system (PACS) for the management, retention, routing, analysis and review of medical images stored in proper DICOM format.		
Risk class	IIb		
Applicable classification rules	11—2		
References to applied CS to which conformity is declared	N/A		
Associated device components	(Trade) Name(s)	Version	UDI-DI
	iQ-WEB	7.2.9	+B403IQWEB72906
	iQ-4VIEW	2.4	+B403IQ4VIEW240-
	iQ-VIEW	4.0	+B403IQVIEW400U
	iQ-ROUTER	5.0	+B403IQROUTER5001

The medical device stated above fulfills the General Safety and Performance Requirements according to Annex I of MDR 2017/745.

Conformity has been established by means of the conformity assessment procedures according to Annex IX of MDR 2017/745 based on the following elements:

- Assessment of the Quality Management System
- Assessment of the Technical Documentation

The license of certification is subject to surveillance by the Notified Body.

DNV MEDCERT GmbH
Pilatuspool 2
20355 Hamburg, Germany
(CE 0482)

The EU Quality Management System Certificate as issued by the Notified Body is valid until 2028-02-14.

This declaration is valid with the date of the signature.

Rostock, 2024-07-11

DocuSigned by:

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Dr. Arpad Bischof
PRRC | Managing Director