

## Compliance declaration for the software product JiveX with

### **E DIN EN 80001**

The requirements of the E DIN EN 80001 draft standard as they apply to VISUS Health IT GmbH as a medical device producer of the JiveX software are met in full.

We hereby declare conformity of the medical device product JiveX with the directive 93/42/EWG and compliance with the specifications of all essential communication interfaces. For further information, the following documents are available:

- ▶ JiveX EG – Declaration of Conformity
- ▶ JiveX DICOM Conformance Statement (English)
- ▶ JiveX HL7 Conformance Statement (English)
- ▶ JiveX IHE Integration Statement (English)
- ▶ Function and interoperability certificate for electronic image archiving (PACS)

Our manuals provide

- ▶ a description of the specific function of the medical device JiveX (representation of image data for diagnosing purposes),
- ▶ the required IT network characteristics,
- ▶ a description of required IT network configurations.

Further requirements, such as the technical specifications of network interfaces are irrelevant for JiveX due to the characteristics of the software.

We do not know about any special remaining risks to be administered by the operator.

As to delivered hardware, we fulfil all requirements placed at us as an IT-supplier. We affirm that the offered / sold hardware and operating systems fulfil the essential system requirements for running JiveX; we do not know of any incompatibilities with, or restrictions for, JiveX.

All technical descriptions and technical manuals provided by the hardware and operating system suppliers are included in the delivery to the customer.

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