

INTERNATIONAL ELECTROTECHNICAL COMMISSION

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**IEC 81001-5-1**  
Edition 1.0 2021-12

**Health software and health IT systems safety, effectiveness and security -  
Part 5-1: Security - Activities in the product life cycle**

**INTERPRETATION SHEET 1**

This interpretation sheet has been prepared by subcommittee 62A: Common aspects of medical equipment, software, and systems, of IEC technical committee 62: Medical equipment, software, and systems.

The text of this interpretation sheet is based on the following documents:

| DISH          | Report on voting |
|---------------|------------------|
| 62A/1692/DISH | 62A/1706/RVDISH  |

Full information on the voting for the approval of this interpretation sheet can be found in the report on voting indicated in the above table.

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This interpretation sheet is intended to clarify the following:

- a) Requirements which are needed to provide essential ACCOMPANYING DOCUMENTATION to the operators of the HEALTH SOFTWARE product regarding the transfer of risk related to software items from the MANUFACTURER to the responsible organization or operator.
- b) Requirements which are needed to maintain SECURITY of the HEALTH SOFTWARE product

**Interpretation of IEC 81001-5-1:2021, Introduction, 0.2**

The HEALTH SOFTWARE is part of a connected and complex healthcare ecosystem, which is integrated into a surrounding HEALTH IT SYSTEM and HEALTH IT INFRASTRUCTURE. ISO 81001-1 provides a definition of the sociotechnical ecosystem in which the HEALTH SOFTWARE operates in, and how to reference the security aspect of the HEALTH SOFTWARE within an IT-system inside a broader HEALTHCARE SYSTEM.