INTERNATIONAL ELECTROTECHNICAL COMMISSION

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IEC 60601-2-2

Edition 6.0 2017-03
Amendment 1 2023-02

Medical electrical equipment - Part 2-2: Particular requirements for the basic safety and essential performance of high frequency surgical equipment and high frequency surgical accessories

INTERPRETATION SHEET 1

This interpretation sheet has been prepared by subcommittee 62D: Particular 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
62D/2255/DISH	62D/2274/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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Interpretation of 201.3.223, 201.3.224, 201.4.1.101, 201.7.9.2.2.101 i), 201.7.9.2.14 k), 202.7.1.2 and the rationales to 201.4.1.101, 201.7.9.2.2.101 i), 201.7.9.2.14 k), Clause 202 of IEC 60601-2-2:2017 and IEC 60601-2-2:2017/AMD1:2023.

This interpretation sheet is intended to clarify the requirements for EMC testing and compatibility.

Definition 201.3.223 HF SURGICAL ACCESSORY

The requirements in this definition of IEC 60601-2-2:2017 are clarified by the following.

The IEC 60601-2-2:2017 defined term HF SURGICAL EQUIPMENT does not modify the IEC 60601-1 definition of medical electrical equipment.

ICS 11.040.30

IEC 60601-2-2:2017-03/AMD1:2023-02/ISH1:2025-11(en-fr)

Definition 201.3.224 HF SURGICAL EQUIPMENT

The requirements in this definition of IEC 60601-2-2:2017 are clarified by the following.

HF SURGICAL ACCESSORIES are not HF SURGICAL EQUIPMENT. This standard defines HF SURGICAL EQUIPMENT and HF SURGICAL ACCESSORY uniquely.

Subclause 201.4.1.101 * Additional conditions for application

The requirements in this subclause of IEC 60601-2-2:2017 are clarified by the following.

It does not exempt HF SURGICAL EQUIPMENT from the requirements of IEC 60601-1-2.

It does not exempt HF SURGICAL ACCESSORIES from the requirements of IEC 60601-1-2.

Subclause 201.7.9.2.2.101 Additional information in instructions for use

The requirements in this subclause of IEC 60601-2-2:2017 and IEC 60601-2-2:2017/AMD1:2023 are clarified by the following.

i) This subclause only requires the manufacturer to provide the length.

Subclause 201.7.9.2.14 *ACCESSORIES, supplementary equipment, used material

The requirements in this subclause of IEC 60601-2-2:2017 and IEC 60601-2-2:2017/AMD1:2023 are clarified by the following.

k) This subclause only requires the manufacturer to provide the length.

Subclause 202.7.1.2 Operating modes

The requirements in this subclause of IEC 60601-2-2:2017 are clarified by the following.

Subclause 202.7.1.2 does not exempt HF SURGICAL ACCESSORIES from the requirements of IEC 60601-1-2, particularly the configuration requirements of subclause 4.3.1.

While HF SURGICAL EQUIPMENT actually meets the definition of CISPR 11 Group 2 equipment, subclause 202.7.1.2 specifies (as does CISPR 11) that when switched on and in idle state, HF SURGICAL EQUIPMENT should meet the limits of CISPR 11 Group 1. For this reason, the accompanying documents should state the limits with which the HF SURGICAL EQUIPMENT complies, but should also state that it is CISPR 11 Group 2 equipment.