DIN EN ISO 80601-2-69:2021-06 (E)

Medical electrical equipment - Part 2-69: Particular requirements for the basic safety and essential performance of oxygen concentrator equipment (ISO 80601-2-69:2020)

Contents

Page

European foreword 4

Foreword 5

Introduction 6

201.1 * Scope, object and related standards 8

201.2 Normative references 10

201.3 Terms and definitions 11

201.4 General requirements 12

201.5 General requirements for testing of *ME equipment* 13

201.6 Classification of *ME equipment* and *ME systems* 13

201.7 *ME equipment* identification, marking and documents 14

201.8 Protection against electrical *hazards* from *ME equipment* 21

201.9 Protection against *mechanical hazards* of *ME equipment* and *ME systems* 21

201.10 Protection against unwanted and excessive radiation *hazards* 23

201.11 Protection against excessive temperatures and other *hazards* 23

201.12 Accuracy of controls and instruments and protection against hazardous outputs 27

201.13 *Hazardous situations* and fault conditions for *ME equipment* 32

201.14 *Programmable electrical medical systems (PEMS)* 32

201.15 Construction of *ME equipment* 32

201.16 *ME systems* 33

201.17 Electromagnetic compatibility of *ME equipment* and *ME systems* 33

201.101 Outlet connector 33

201.102 Requirements for parts and *accessories* 34

201.103 Functional connection 35

201.104 * Indication of duration of operation 35

201.105 Integrated conserving equipment function 36

202 Electromagnetic disturbances – Requirements and tests 36

202.4.3.1 * Configurations 36

206 Usability 37

211 Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment 38

211.4.2.2 Environmental operating conditions 38

Annex C (informative) **Guide to marking and labelling requirements for *ME equipment* and *ME systems*** **39**

Annex D (informative) **Symbols on marking** **44**

Annex AA (informative) **Particular guidance and rationale** **46**

Annex BB (informative) **Reference to the IMDRF *essential principles* and labelling guidances** **53**

Annex CC (info rmative) **Reference to the *essential principles*** **58**

Annex DD (informative) **Reference to the general safety and performance requirements** **62**

Annex EE (informative) **Terminology — alphabetized index of defined terms** **66**

Bibliography **69**