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Part B: Supplementary Information Sheet (SIS)

FR Recognition List Number 000

Date of Entry 04/03/2023

FR Recognition Number 19-49

Standard (Included in [ASCA](#) pilot)

IEC 60601-1 Edition 3.2 2020-08 CONSOLIDATED VERSION

Medical electrical equipment - Part 1: General requirements for basic safety and essential performance

- Note: This standard is recognized with relevant US national differences applied, see reference #1 and #2 in the Relevant FDA Guidance and/or Supportive Publication section below

Scope/Abstract

Iec 60601 3rd Edition Fda

Katrin Zwirgmaier

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