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| **Standard** | **Version** | **Amendment** | **Title** | **Applicable** |
| EN ISO 11135 | 2014 | A1:2019 | Sterilization of health care products - Ethylene oxide - Requirements for the development, validation and routine control of a sterilization process for medical devices  |  |
| EN ISO 11137-1 | 2015 | A2:2019 | Sterilization of health care products - Radiation - Part1: Requirements for development, validation and routine control of a sterilization process for medical devices |  |
| EN ISO 11737-1 | 2018 | A1:2021 | Sterilization of health care products - Microbiological methods - Part 1: Determination of a population of microorganisms on products |  |
| EN ISO 11737-2 | 2020 |  | Sterilization of health care products - Microbiological methods - Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process |  |
| EN ISO 13408-6 | 2021 |  | Aseptic processing of health care products - Part 6: Isolator systems |  |
| EN ISO 13485 | 2016 | A11:2021 | Medical devices - Quality management systems - Requirements for regulatory purposes |  |
| EN ISO 14971 | 2019 | A11:2021 | Medical devices – Application of risk management to medical devices |  |
| EN ISO 15223-1 | 2021 |  | Medical devices - Symbols to be used with medical device labels, labeling and information to be supplied - Part 1: General requirements  |  |
| EN ISO 17511 | 2021 |  | In vitro diagnostic medical devices – Requirements for establishing metrological traceability of values assigned to calibrators, trueness control materials and human samples |  |
| EN ISO 25424 | 2019 | A1:2022 | Sterilization of health care products – Low temperature steam and formaldehyde – Requirements for development, validation and routine control of a sterilisation process for medical devices (ISO 25424:2018) |  |