Det globale perspektivet

Internasjonale standarder for medisinsk utstyr – status og utvikling globalt

Frode Liland, Laerdal Global Health AS

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Introduksjon – Frode Liland

2014 – (2025) - SN/K 122 - ISO TC 121 Anaesthetic and respiratory equipment

- SC 3: Ventilatorer, luftveier
- SC 2: Luftveisutstyr

2001 - (2025) - Laerdal Medical / Laerdal Global Health

- Produktutvikler / Prosjektleder / Teknisk Produktsjef

1996 – 2001 - Automotive, Mobiltelefon produksjon

1995 - Sivilingeniør “Maskin” – Produktutvikling og materialteknologi.

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Laerdal's medisinske utstyr (typer)

ISO 10651-4

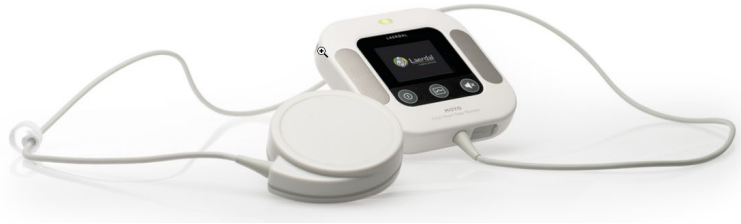
ASTM F2726

ASTM 1559

ISO 10079-2

Med produktstandard

ISO 10079-1



IEC 60601-2-37

Med elektronikk

(ISO/PWI 22541)

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Laerdal's globale lokasjoner

2200 ansatte

+ 50 nasjonaliteter

26 land

Historie: 1990-tallet –
Regionale standarder blir synkronisert, deretter erstattet

1967-1976-1984–2003-2010-2014-2016-2023-2025-(2026)

AS 2488—1995

Australian Standar

Resuscitators inten
with humans

First published as AS 2488—1981
Second edition 1995

Designation: F 920 – 85

Standard Specification for
Minimum Performance and Safety Requirements for
Resuscitators Intended for Use with Humans[1]

This standard is issued under the fixed designation F 920; the number immediately following the designation indicates the year of original adoption or, in the case of revision, the year of last revision. A number in parentheses indicates the year of last reapproval. A superscript epsilon (ε) indicates an editorial change since the last revision or reapproval.

1. Scope

1.1 This specification is intended to establish minimum performance and safety requirements relative to the function of pulmonary resuscitators. It is based on parameters achievable by existing technology and is written with the best available information. This specification represents the state of the art at the time it is published. There is no intent to discourage or impede future innovation or development of resuscitators.

1.2 This specification deals with the performance of operator-powered and gas-powered or electrically-powered pulmonary resuscitators. These devices are usually portable and designed for use in emergency situations to provide lung ventilation to individuals whose breathing is inadequate. Resuscitators intended for use on all age groups are included within the scope of this specification.

1.3 This specification does not deal with devices which have been designed specifically to deliver gases to a patient who is breathing adequately, nor to devices which are designed to assist or provide for the ventilation of a patient for an extended period of time, that is, critical care ventilators.

1.4 The following precautionary caveat pertains only to the test method portion, Section 6, of this specification: *This standard may involve hazardous materials, operations, and equipment. This standard does not purport to address all of the safety problems associated with its use. It is the responsibility of whoever uses this standard to consult and establish appropriate safety and health practices and determine the applicability of regulatory limitations prior to use.*

INTERNATIONAL STANDARD

ISO 8382
First edition
1988-12-15

INTERNATIONAL ORGANIZATION FOR STANDARDIZATION
ORGANISATION INTERNATIONALE DE NORMALISATION
МЕЖДУНАРОДНАЯ ОРГАНИЗАЦИЯ ПО СТАНДАРТИЗАЦИИ

Resuscitators intended for use with humans

Ressuscitateurs destinés aux êtres humains

Kliniske
retningslinjer

BRITISH STANDARD

BS EN ISO
10651-4:2009

Lung ventilators

Part 4: Particular requirements for operator-powered resuscitators (ISO 10651-4:2002)

Oppdatering 2023

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Global deltakelse i ISO-komiteer

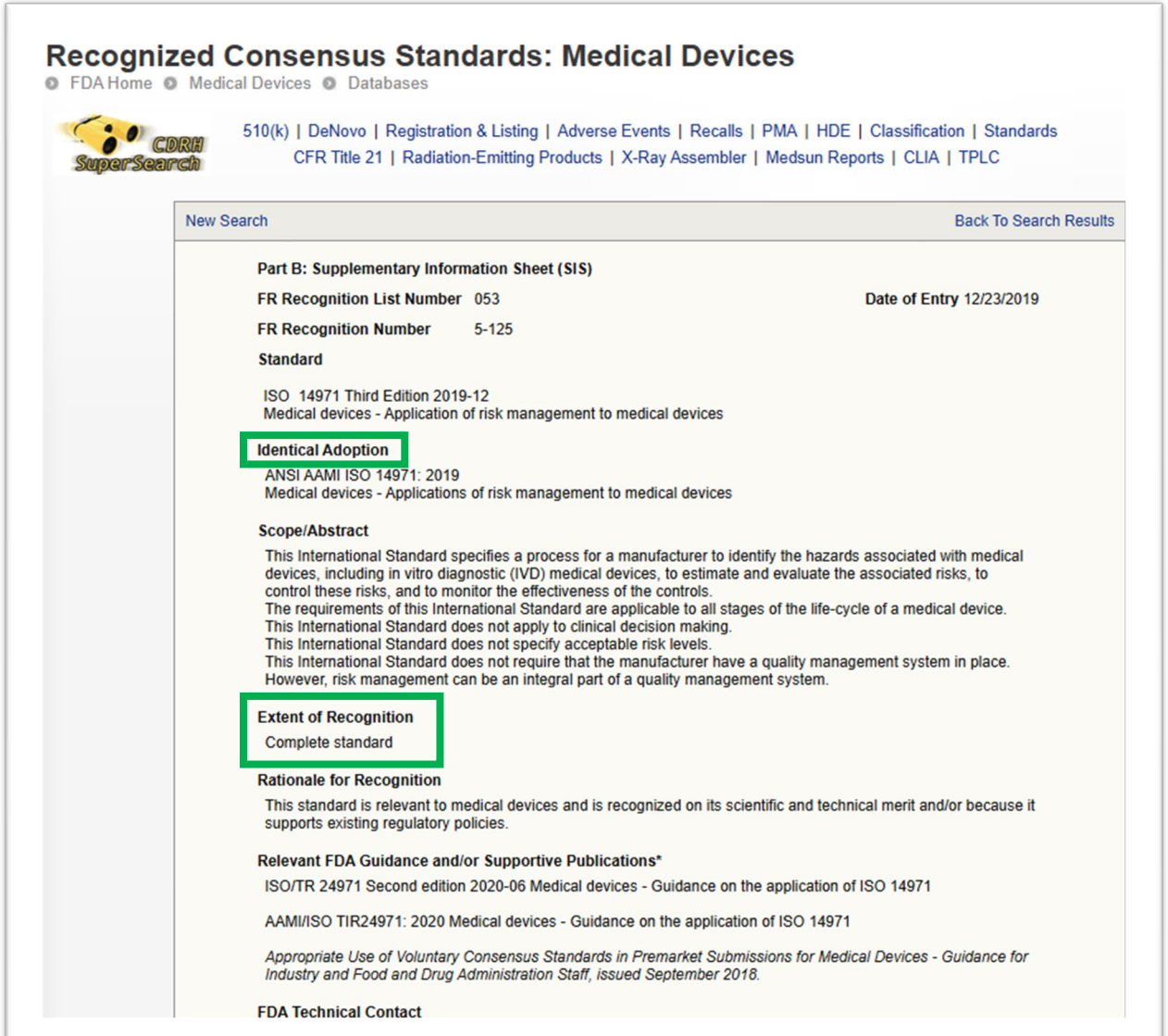
Bidrar til at nye ISO-standarder ikke trenger nasjonale varianter

Eksempel aktive land:

- Australia
- Japan
- Kina
- India
- Saudi Arabia
- Canada
- US
- Frankrike
- Irland
- New Zealand
- Norge
- Tyskland
- UK

Kompetanse blant delegater:

- Klinikere
- Regulatorisk
- Industri



Recognized Consensus Standards: Medical Devices

FDA Home | Medical Devices | Databases

510(k) | DeNovo | Registration & Listing | Adverse Events | Recalls | PMA | HDE | Classification | Standards
CFR Title 21 | Radiation-Emitting Products | X-Ray Assembler | Medsun Reports | CLIA | TPLC

New Search | Back To Search Results

Part B: Supplementary Information Sheet (SIS)

FR Recognition List Number 053 **Date of Entry** 12/23/2019

FR Recognition Number 5-125

Standard

ISO 14971 Third Edition 2019-12
Medical devices - Application of risk management to medical devices

Identical Adoption

ANSI AAMI ISO 14971: 2019
Medical devices - Applications of risk management to medical devices

Scope/Abstract

This International Standard specifies a process for a manufacturer to identify the hazards associated with medical devices, including in vitro diagnostic (IVD) medical devices, to estimate and evaluate the associated risks, to control these risks, and to monitor the effectiveness of the controls.
The requirements of this International Standard are applicable to all stages of the life-cycle of a medical device.
This International Standard does not apply to clinical decision making.
This International Standard does not specify acceptable risk levels.
This International Standard does not require that the manufacturer have a quality management system in place. However, risk management can be an integral part of a quality management system.

Extent of Recognition

Complete standard

Rationale for Recognition

This standard is relevant to medical devices and is recognized on its scientific and technical merit and/or because it supports existing regulatory policies.

Relevant FDA Guidance and/or Supportive Publications*

ISO/TR 24971 Second edition 2020-06 Medical devices - Guidance on the application of ISO 14971

AAMI/ISO TIR24971: 2020 Medical devices - Guidance on the application of ISO 14971

Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices - Guidance for Industry and Food and Drug Administration Staff, issued September 2018.

FDA Technical Contact

Standard-versjoner i ulike markeder

International Standard Number	Standard Name	**Most recent version from developing committee** ISO - International Organization for Standardization Checked 2025-03-13	**Most recent EN version** Standard Norge Checked 2025-03-13	**Harmonized under EU MDD** Implementing decision - 2020/437 - EN - EUR-Lex Current consolidated version: 15/04/2021	**Harmonized under EU MDR** DocsRoom - European Commission Last update: 09/10/2024	**Recognized by US FDA** Recognized Consensus Standards: Medical Devices Checked: 2025-05-26	**Recognized by Australian TGA** Home | Standards Australia Checked 2025-03-13	**Recognized by Health Canada** List of federally recognized standards for medical devices - Canada.ca	**Recognized by Health Authorities Singapore** *Not considered in this revision.*	**Applied Version**	**Justification**
Development standards											
ISO 14971	Medical devices – Application of risk management to medical devices	ISO 14971 :2019	EN ISO 14971 :2019 /A11:2021	EN ISO 14971: 2012 (ISO 14971: 2007)	EN ISO 14971 :2019 /A11:2021 (ISO 14971: 2019)	ISO 14971 Third Edition 2019-12	AS ISO 14971: 2020 (ISO 14971: 2019)	ISO 14971	SS ISO 14971:2020	EN ISO 14971:2019/ A11:2021	Applied to all devices and accessories.
IEC 62366-1	Medical Devices - Application of usability engineering to medical devices	IEC 62366-1: 2015 +Cor 1:2016 +Amd1:2020	EN 62366-1 :2015 +A1:2020	EN 62366 :2008 (IEC 62366 :2007)	No	IEC 62366-1 Edition 1.1 2020-06 CONSOLIDATED VERSION	IEC 62366-1:2015 +Amd1:2020	IEC 62366-1	SS IEC 62366-1 (+A1):2018	IEC 62366-1:2015 +Amd1:2020	Applied as state of the art to all devices and accessories.

EU harmoniseringsprosess ved MDD/MDR har gått i stå

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Hovedfelt av generelle standarder

Generelle standarder

- ISO 14971 – Risk Management
- IEC 62366-1 – Usability
- ISO 10993-1 – Biological safety
- IEC 60601-1 – Electrical safety
- IEC 62304 – Medical device software
- ISO 20417 – Labeling
- Radio (EN / FCC)
- Reprosessering (AAMI)
- MRI compatibility (ASTM)
- Cybersecurity

Eksempel på ny generell standard på SC-nivå

ISO 18190 – Anaesthetic and respiratory equipment — General requirements for airway devices and related equipment:

- 2016: Gjelder kun for produktstandarder som referer til denne (2)
- 2024: Scope endret til alle produkter.

Mange produkt-typer er ikke er dekket av produktstandarder; men kan i stor grad dekkes ved nye generelle standarder;

Produktstandarder

- Kan da forenkles og referere til den generelle.
- Fokusere på unike egenskaper og krav ved produktet.

Nye standarder som gir støtte til regulatoriske sjekklister

- Annex – Mapping til
  - IMDRF *essential principles*
  - Essential principles ISO 16142-1:2016
  - EU GSPRs (eksempel ISO 10651-4:2023, Annex F)

Table F.1 — Correspondence between this document and the general safety and performance requirements

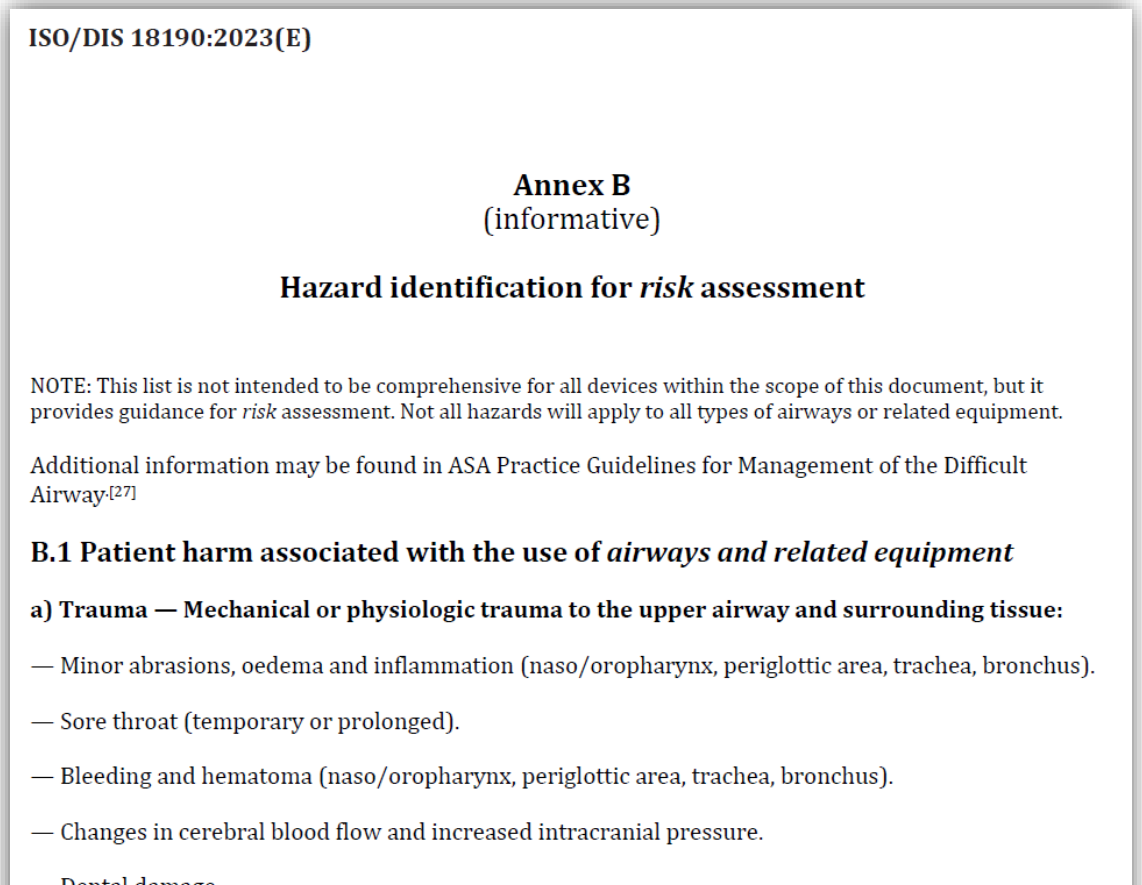
General safety and performance requirements of regulation (EU) 2017/745, Annex I[23]	Corresponding clause(s)/sub-clause(s) of this document	Qualifying remarks/Notes
3	4.1	
4	4.1	
5 a)	12 b), 12 c)	Addresses requirements to identify and validate ergonomic aspects of the use of the device related to the primary operating functions
6	4.6.3, 4.6.4	Addresses shelf-life and expected lifetime in operation requirements
7	4.6.1	Addresses the storage conditions per the design of the user-powered resuscitator – does not address manufacturing
10.1 a)	11	Addresses toxicity relating to design
10.1 b)	11	Only the part relating to design is addressed. Covered with respect to biocompatibility evaluation for direct patient contact with the resuscitator and its accessories; and following exposure to any substance with which the resuscitator's gas pathways can come into contact in normal use
10.1 d)	10	Only the part relating to design is addressed. Covered only for processes related to the reuse of reusable resusci-

Risk Management

ISO 14971:2019 – Medical Devices – Application of Risk Management

ISO/TR 24971:2020 Guidance

Generelle standarder – gir hjelp til Hazard identification.



ISO/DIS 18190:2023(E)

Annex B
(informative)

Hazard identification for *risk* assessment

NOTE: This list is not intended to be comprehensive for all devices within the scope of this document, but it provides guidance for *risk* assessment. Not all hazards will apply to all types of airways or related equipment.

Additional information may be found in ASA Practice Guidelines for Management of the Difficult Airway.[27]

B.1 Patient harm associated with the use of *airways and related equipment*

a) Trauma — Mechanical or physiologic trauma to the upper airway and surrounding tissue:

— Minor abrasions, oedema and inflammation (naso/oropharynx, periglottic area, trachea, bronchus).

— Sore throat (temporary or prolonged).

— Bleeding and hematoma (naso/oropharynx, periglottic area, trachea, bronchus).

— Changes in cerebral blood flow and increased intracranial pressure.

— Dental damage

Usability / Human Factors

AAMI HE48:1988, titled "Human Factors Engineering Guidelines and Preferred Practices for the Design of Medical Devices"

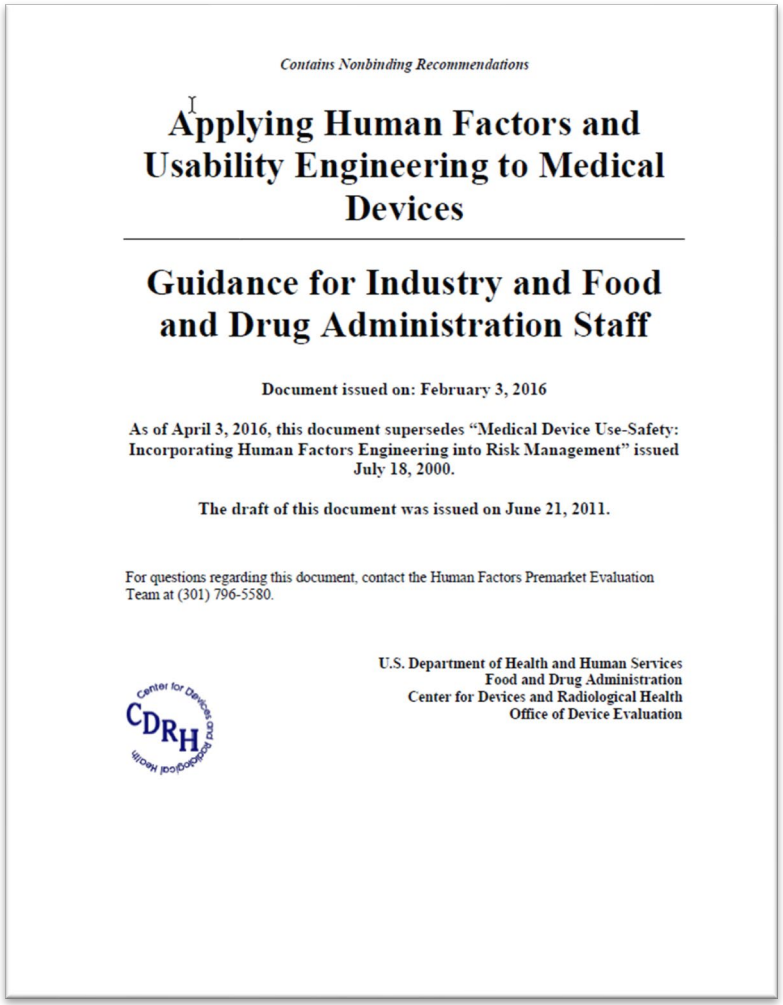
AAMI HE75:2009
Human factors engineering - Design of medical devices

IEC 62366:2007
IEC 62366-1:2015
Medical devices - Part 1: Application of usability engineering to medical devices

US FDA Guidance (2016).
Applying Human Factors and Usability Engineering to Medical Devices

EU MDR siden 2017.

IEC/CD TS 62366-2:2024
Medical devices – Part 2: Guidance on the application of usability engineering to medical devices



Contains Nonbinding Recommendations

Applying Human Factors and Usability Engineering to Medical Devices

Guidance for Industry and Food and Drug Administration Staff

Document issued on: February 3, 2016

As of April 3, 2016, this document supersedes "Medical Device Use-Safety: Incorporating Human Factors Engineering into Risk Management" issued July 18, 2000.

The draft of this document was issued on June 21, 2011.

For questions regarding this document, contact the Human Factors Premarket Evaluation Team at (301) 796-5580.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health
Office of Device Evaluation

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Electrical safety

IEC 60601-1:2005 - Medical electrical equipment - Part 1: General requirements for basic safety and essential performance

- 4th Edition i arbeide, 12 arbeidsgrupper.
- Oppdatert struktur, nye teknologier, cybersecurity
- Norge: NEK, 3 norske deltakere

En rekke produktstandarder blir modernisert og eller oppdatert.
Komplettering for å dekke flere varianter.

--

Risiko for overlapp: Avklaring om IEC versus ISO fordeling, for elektrifiserte produkter.

Eksempel: Forstøvere (nebulizers),

- Kan eksistere som rene mekaniske produkter, og resultatet er også mekanisk (ISO)
- Når pumpen som genererer trykk til forstøveren er elektrisk … (IEC)

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Cybersecurity

US FDA tidlig ute med Guidance (2005) - OTS

EU MDR: MDCG 2019-16 - Guidance on Cybersecurity for medical devices

IEC/TR 60601-4-5:2021 - Medical electrical equipment - Part 4-5: Guidance and interpretation - Safety-related technical security specifications

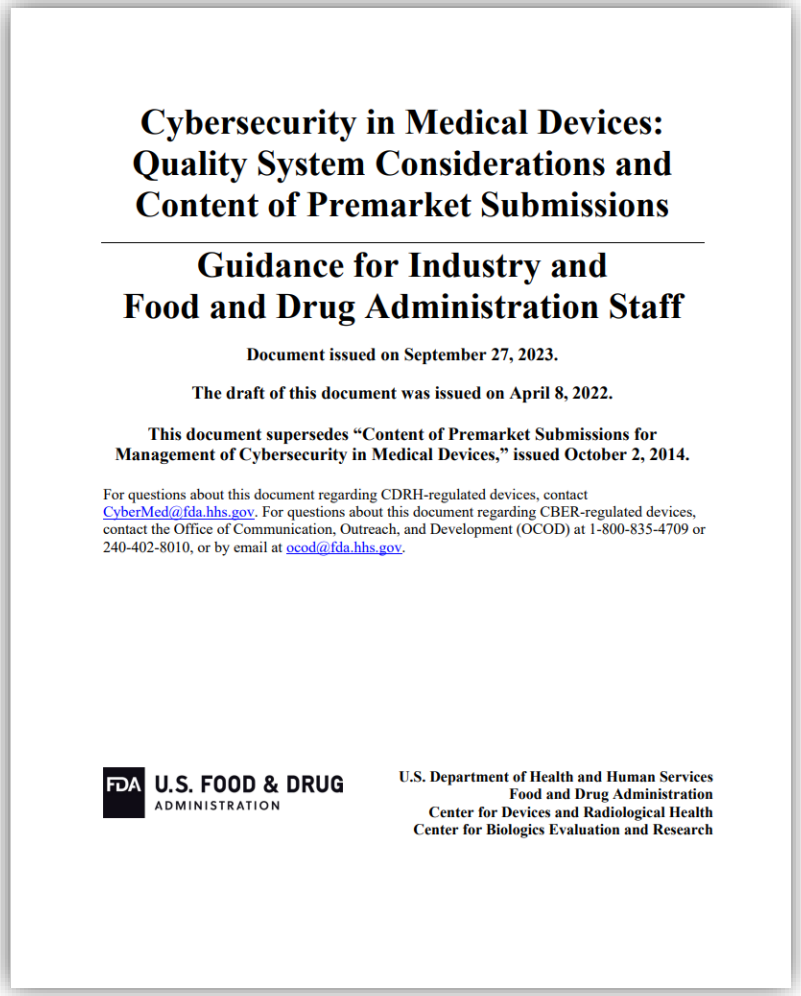
IEC 81001-5-1:2021 - Health software and health IT systems safety, effectiveness and security - Part 5-1: Security — Activities in the product life cycle

Tillegg i dokumentasjon

- Vurdert i design (software, hardware, App)
- Inkludert i risiko analyse
- Cybersecurity Lifecycle plan, post-market surveillance
- Cybersecurity threat model
    - STRIDE - Model for identifying security threats. (Wikipedia)

Threat	Desired property	Threat Definition
Spoofing	Authenticity	Pretending to be something or someone other than yourself
Tampering	Integrity	Modifying something on disk, network, memory, or elsewhere
Repudiation	Non-repudiability	Claiming that you didn't do something or were not responsible; can be honest or false
Information disclosure	Confidentiality	Someone obtaining information they are not authorized to access
Denial of service	Availability	Exhausting resources needed to provide service
Elevation of privilege	Authorization	Allowing someone to do something they are not authorized to do

- Cybersecurity Penetration test



Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions

Guidance for Industry and Food and Drug Administration Staff

Document issued on September 27, 2023.

The draft of this document was issued on April 8, 2022.

This document supersedes "Content of Premarket Submissions for Management of Cybersecurity in Medical Devices," issued October 2, 2014.

For questions about this document regarding CDRH-regulated devices, contact CyberMed@fda.hhs.gov. For questions about this document regarding CBER-regulated devices, contact the Office of Communication, Outreach, and Development (OCOD) at 1-800-835-4709 or 240-402-8010, or by email at ocod@fda.hhs.gov.

FDA U.S. FOOD & DRUG ADMINISTRATION

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health
Center for Biologics Evaluation and Research

Clinical Evaluation

EU MDR Clinical Evaluation

- MEDDEV 2.7/1 revision 4 (2016)
- Erstattes av MDCG (Medical Device Coordination Group) guidance.

ISO standarder brukt i forbindelse med Clinical Evaluation

ISO 14971:2019 – Application of risk management to medical devices

ISO 14155:2020 - Clinical investigation of medical devices for human subjects — Good clinical practice

ISO/TR 20416:2020 – Post-market surveillance for medical devices

ISO/CD 18969 - Clinical evaluation of medical devices

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Sustainability

Lokal regulering starter krav som støtter til sustainability;

- EU WEEE Directive – elektrisk og elektronisk avfall
- EU Battery Regulation 2023/1542
    - Alle batterier importert til eller laget i EU, må ha CE-merke (og altså oppfylle krav til materialer).
    - Alle batterier må kunne gjenvinnes.
    - Bruker må kunne bytte batterier i alle apparater.

Medical Devices fremstår som "urørt" i forhold til sustainability;

- Pasient-sikkerhet rangerer høyere, f.eks. infeksjonsrisiko.
- Produsenter må sikre at produktene oppfyller krav, er biokompatible og rene.
- Resirkulert materiale i medisinske produkter er i praksis utenkelig, på grunn av bevisbyrde for produsenter.
- Gjenbrukbare produkter finnes ofte som alternativ til engangsprodukter. Kunden *kan* velge.
    - Standarder for reprosessering og human factors finnes.

- TC121 SC2 vil se på feltet. Hva kan gjøres med standarder?

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Biological safety: Fra ny bekymring til ny standard

- 2013: Vi leverer US FDA 510(k) søknad for en ny variant resuscitator, som oppfyller alle kjente krav (*derav ISO 10993* biokompatibilitet).
- FDA svarer med ny uventet liste over krav i forhold til inspiratorisk gass-vei til pasienten;
  - «Lekkasje av kjemikalier inn i kondensat, giftighet», «Partikler», seinere «flyktige gasser»).
- Vi fant at det var en ISO arbeidsgruppe for en ny standard-serie, ISO 18562, hvor FDA deltok.
  - Sekretæren fortalte at slike «bekymringer» i godkjenninger nå var typisk for ventilator-godkjenninger.
  - Industrien selv tok initiativ til å utvikle ny standard, slik at krav kunne bli definert og være likt for alle.
- 2014: Laerdal meldte seg inn i SN og ISO WG, fikk innsikt og fikk delta i review.
- 2014: 12 måneders ekstra test-utvikling og testing (som prøvekanin?) og flere oppklaringsmøter med FDA
- 2015: Godkjent produktet
  - Bidro til standarden om testmetoder.
- 2017: *ISO 18562-1*, -2, -3, -4 standarder publisert.
- 2024: Standarder revidert. (FDA: *Partial recognition*)

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Testing til standarder

CB sertifikat *(IECEE) for elektrisk utstyr*

--

Bruk av *akkrediterte test-hus*; finnes kanskje ikke til nye produktstandarder, eller spesielle produkter.

--

Begrunnelse for intern testing, som alternativ;

1. Kvalitetssystem som dekker produkttesting.
2. ISO 13485 sertifisering for utvikling av produkt-typen.
3. Uavhengighet av test-personale.
4. Kalibrert og egnet testutstyr.
5. Kompetanse innen relevante felt (utdanning and arbeidserfaring).
6. Rapport-format som støtter at standarden (evt. egne krav) er oppfylt, med konklusjon og begrunnelser.

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'This could lead to harm': Half of resuscitator bags for babies faulty

The Sydney Morning Herald

By Esther Han

21 October 2018 — 4:25pm

Half of the self-inflatable resuscitation bags used on newborn babies who are not breathing or in cardiac arrest are defective and potentially dangerous, researchers say.

After a NSW Health recommendation that hospitals consider using disposable, single-use self-inflating bags instead of reusable ones "from a cost perspective", researchers at Sydney University and Westmead Hospital decided to test 20 models on the international market.

Around the world, five million babies die in the first two days of life every year. SHUTTERSTOCK

In a study published in the BMJ journal *Archives of Disease in Childhood: Fetal and Neonatal*, they reported two of four reusable models and eight of 16 disposable models failed safety and reliability tests, even though they complied with international standards.

"Doctors, nurses and midwives may be trying to resuscitate a baby and because they don't know

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