AGENDA NEN-Klankbordgroep

Datum: 1 Mei 2024
Tijd : 13.00-16.00 uur
Locatie: UMC Utrecht, Heidelberglaan 100, 3584 CX Utrecht
Neude vergaderzaal,
bij de hoofdingang direct naar links en na 100 meter aan de linkerhand.

Vertegenwoordiging:

Normcommissie 301.002 medische hulpmiddelen algemeen (horizontale normen)

Jan Hazelhof (VDSMH) (VZ)

Normcommissie 301.081 steriliseren en steriliteit

Lia Mantingh (SVN); Han Loman (SVN); Martin Veen (SVN); Lucie van der Schaaf (SVN); Carol te Beest (VDSMH); Corinne Riekwel (VDSMH); Jeroen de Geus (VDSMH); Mariette Jungblut (LUMC) Ummiye van der Velden (LUMC); Kees van der Meulen (VDSMH) (vice-VZ); Diana Bijl (Diana Bijl consultancy) (VZ)

Platform duurzaamheid medische hulpmiddelen

Corinne Riekwel (SVN); Diana Bulkmans (VDSMH)

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1. **OPENING.**

2. **VASTSTELLEN AGENDA.**

3. **MEDEDELINGEN.**

4. **NORMEN EN RICHTLIJNEN TER BESPREKING, STERILISEREN EN STERILITEIT.**

   a. **Internationale ontwikkelingen.**

Norm	Titel	sluitingsdatum
EN868-10:2018	Packaging for terminally sterilized medical devices - Part 10: Adhesive coated nonwoven materials of polyolefines - Requirements and test methods	2024-05-20
EN868-5:2018	Packaging for terminally sterilized medical devices - Part 5: Sealable pouches and reels of porous materials and plastic film construction - Requirements and test methods	2024-05-20
EN868-8:2018	Packaging for terminally sterilized medical devices - Part 8: Re-usable sterilization containers for steam sterilizers conforming to EN 285 - Requirements and test methods	2024-05-20

EN868-9:2018	Packaging for terminally sterilized medical devices - Part 9: Uncoated nonwoven materials of polyolefines - Requirements and test methods	2024-05-20
ISO 11138-7:2019	Sterilization of health care products – Biological indicators – Part 7: Guidance for the selection, use and interpretation of results	2024-05-20
ISO 11607-1:2019 (Ed 2)	Packaging for terminally sterilized medical devices – Part 1: Requirements for materials, sterile barrier systems and packaging systems	2024-05-20
ISO 11607-2:2019 (Ed 2)	Packaging for terminally sterilized medical devices – Part 2: Validation requirements for forming, sealing and assembly processes	2024-05-20
ISO/TS 22421:	Sterilization of health care products – Common requirements for sterilizers for terminal sterilization of medical devices in health care facilities	2024-05-20
ISO/TS 22456:2021	Sterilization of healthcare products – Microbiological methods– Guidance on conducting bioburden determinations and tests of sterility for biologics and tissue-based products	2024-05-20
FprEN ISO 15883-1 ISO/FDIS 15883-1 (Ed 2)	Washer-disinfectors - Part 1: General requirements, terms and definitions and tests (ISO/FDIS 15883-1:2024)	2024-05-28

b. **Nationale ontwikkelingen.**
Indien er tijd over is worden hier de lopende thema's benoemd.

5. NORMEN EN RICHTLIJNEN TER BESPREKING, HORIZONTALE NORMEN MEDISCHE HULPMIDDELEN ALGEMEEN.

Indien er tijd over is worden hier de lopende thema's benoemd.

6. PLATFORM DUURZAAMHEID MEDISCHE HULPMIDDELEN.

Indien er tijd over is worden hier de lopende thema's benoemd.

7. NOTULEN VORIGE BIJEENKOMST.

8. RONDVRAAG EN SLUITING.