

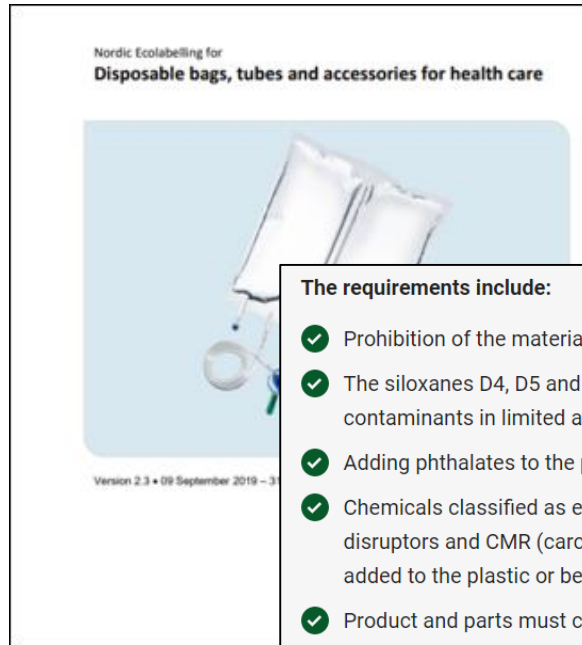


Addressing chemistry in sustainable medical textiles in Norwegian hospitals

HCWH Webinar 17 March 2022

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Use reputable, transparent third-party certifications when available

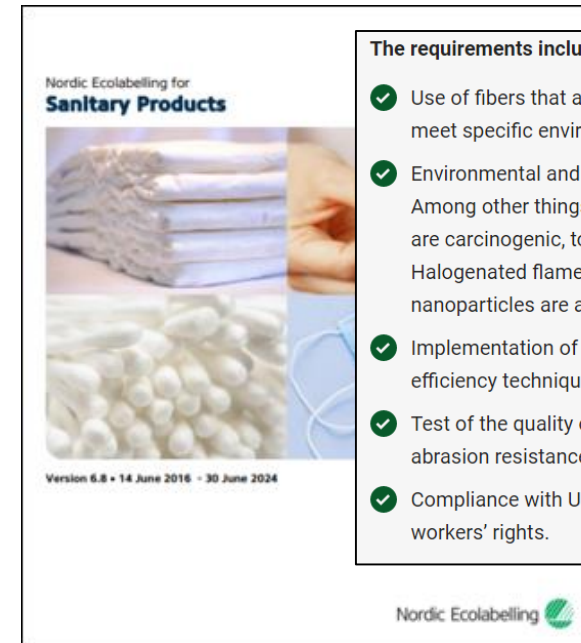


- The requirements include:**
- ✓ Prohibition of the materials PVC and latex
 - ✓ The siloxanes D4, D5 and D6 is not allowed in silicone, but can be in the silicone as contaminants in limited amounts
 - ✓ Adding phthalates to the plastic is prohibited
 - ✓ Chemicals classified as environmentally harmful, toxic, allergenic, endocrine disruptors and CMR (carcinogenic, mutagenic, toxic for reproduction) cannot be added to the plastic or be part of the adhesive
 - ✓ Product and parts must comply with EU Medical Products Directive (2001/83 / EC) and/or Medical Devices Regulation (2017/745 / EU)

Peritoneal dialysis

Nordic Swan on all products (Vingmed AS)

The ISO 14024 standard is “a voluntary, multiple-criteria based, third party program that awards a license that authorizes the use of environmental labels on products indicating overall environmental preferability of a product within a particular product category based on life cycle considerations.”



- The requirements include:**
- ✓ Use of fibers that are either organic, recycled or based on renewable resources and meet specific environmental requirements.
 - ✓ Environmental and health properties of all chemicals used in the textile production. Among other things, the Nordic Swan Ecolabel forbids the use of substances that are carcinogenic, toxic to reproduction or can damage genetic material. Halogenated flame retardants fluorinated, and antibacterial additives incl. nanoparticles are also forbidden.
 - ✓ Implementation of a minimum of BAT (best available technology) water and energy efficiency techniques or local production of solar energy in textile production.
 - ✓ Test of the quality of the textile, e.g., dimensional change, color fastness and abrasion resistance.
 - ✓ Compliance with UN's International Labour Organization (ILO) conventions on workers' rights.

Hygiene products: infant/children diapers, incontinence care products, soaps/creams/toothpaste, disposable covers

Nordic Swan on all products

Ecolabeled products in use

MEDICAL TEXTILES CAN BE GROUPED INTO SEVEN CATEGORIES:^{7a}



- **HEALTHCARE AND HYGIENE PRODUCTS**

e.g. bedding, clothing, surgical gowns, wipes, and other disposable products

- **EXTRACORPOREAL DEVICES**

e.g. artificial organs such as kidney, liver, lungs, or pacemakers.

- **IMPLANTABLE MATERIALS**

e.g. sutures, vascular grafts, scaffolds.



- **NON-IMPLANTABLE MATERIALS**

e.g. wound dressings, bandages, plasters, pressure garments.

- **INTELLIGENT MEDICAL AND HEALTHCARE TEXTILES**



- **TEXTILES IN HEALTHCARE ENVIRONMENTS**

e.g. furnishing fabrics, textiles in fixtures and fittings.

- **ENVIRONMENTAL HYGIENE CONTROL COMPONENTS**

e.g. air filters.

- Bedding
- Single use bedding for operations
- Clothing for staff and patients
- Single use clothing for patients

- Bandages
- Plasters

- Mattresses
- Furniture

This report provides an overview for healthcare and hygiene products only.

The use of the European healthcare's phase out list for chemicals of concern



Health Care Without Harm Europe

European healthcare's phase-out list for chemicals of concern

29 November 2021

The European healthcare sector seeks to phase out chemicals of concern from supply chains and medical products and accelerate the phase-out of the highest priority chemicals of concern.

The healthcare sector will continue working with suppliers to achieve this goal. Exemptions to the criteria will be made when safer alternatives do not exist and when specially requested in tenders for essential use.

Chemicals of concern criteria:
Note limit values where indicated.

- 1. Candidate list of substances of very high concern (SVHCS)** – All articles or component articles of a complex article do not contain substances listed on the [Candidate List](#)¹ of the EU chemicals regulation REACH (Registration, Evaluation, Authorisation and Restriction of Chemicals EC 1907/2006) over 0.1% weight by weight (w/w).
- 2. Carcinogenic, mutagenic or substances toxic to reproduction (CMR substances of category 1A or 1B)** – All articles in accordance with Article 52 and 10.4.1 of Annex I of the [Medical Device Regulation](#) (MDR)² do not contain substances which are CMR of category 1A or 1B in accordance with Part 3 of Annex VI to Regulation (EC) No 1272/2008 (CLP) over 0.1% (w/w).
- 3. Polyvinyl chloride (PVC)** – All articles or component articles of a complex article do not contain PVC.
- 4. Phthalates** – All articles or component articles of a complex article do not contain Phthalates listed on the Candidate List or [Restriction List](#)³ of the REACH Regulation, nor on the [ChemSec SIN List](#)⁴ over 0.1% (w/w).

¹ Candidate List: echa.europa.eu/da/candidate-list-table
² The MDR eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32017R0745 Endocrine-disrupting substances in the MDR are covered by the Candidate List and the restricted Phthalates.
³ Restriction List: echa.europa.eu/da/substances-restricted-under-reach
⁴ ChemSec SIN List: sinlist.chemsec.org

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- 5. Bisphenols** – All articles or component articles of a complex article do not contain leachable Bisphenols (not bound to the material) exceeding a 0.1 mg/l (migration limit).
- 6. Flame retardants** – All articles or component articles of a complex article do not contain flame retardants, unless specifically requested.

When flame retardancy is requested, substances on the Candidate List, the Restriction List, or the SIN List over 0.1% (w/w) should not be used.
- 7. Antimicrobial agents** – All articles or component articles of a complex article do not contain intentionally added antimicrobial agents to reduce surface pathogens, unless specifically requested.
- 8. Per- and polyfluoroalkyl substances (PFAS)**^{*} – All articles or component articles of a complex article do not contain stain- or water-repellent treatments that contain total PFAS over 0.1% (w/w).

^{*} PFAS, as defined by the OECD: pecd.org/officialdocuments/publicdisplaydocumentpdf/?cote=ENV/CBC/MONO/2021/258&docLanguage=en

Example: Medical textiles in most recent tender for **operation products**

Delkontrakt 1	Bordtoppdekking
Delkontrakt 2	C-buetrekk
Delkontrakt 3	Intraoperative ultralydprobetrekk
Delkontrakt 4	Kameratrekk
Delkontrakt 5	Lampehåndtaktrekk
Delkontrakt 6	Mikroskoptrekk
Delkontrakt 7	Kompresser og tuffere gas og nonwoven
Delkontrakt 8	Operasjonskompresser gas
Delkontrakt 9	Operasjonstuffere gas
Delkontrakt 10	Operasjonskompresser nonwoven
Delkontrakt 11	Assistansebordposer
Delkontrakt 12	Benposer
Delkontrakt 13	Dekkestykker
Delkontrakt 14	Hullduk
Delkontrakt 15	Innsnittsduker
Delkontrakt 16	Instrumentbordlaken
Delkontrakt 17	Operasjonstape
Delkontrakt 18	Oppdekkingsprodukter
Delkontrakt 19	Oppdekkingssett
Delkontrakt 20	Slangeholder operasjon

Delkontrakt 21	Spesiallaken
Delkontrakt 22	Splittlaken
Delkontrakt 23	Litotomisett
Delkontrakt 24	Sug- og diatermipose
Delkontrakt 25	Transparente dekkeprodukter
Delkontrakt 26	Væskeoppsamlingspose operasjon
Delkontrakt 27	Instrumentposer
Delkontrakt 28	Sugemunnstykker
Delkontrakt 29	Sugeposer og beholdere med tilbehør
Delkontrakt 30	Sugesett
Delkontrakt 31	Sugeslanger
Delkontrakt 32	Bomullspader og pinner
Delkontrakt 33	Irrigasjonssett
Delkontrakt 34	Kniv- og nålebokser
Delkontrakt 35	Knivblad
Delkontrakt 36	Martinsbind
Delkontrakt 37	Merkepenn operasjon
Delkontrakt 38	Tourniquet Blodtomhetsmansjett
Delkontrakt 39	Skalpeller
Delkontrakt 40	Leiringsprodukter, reimer
Delkontrakt 41	Leringsprodukter, engangsputer og madrasser

Example: Requirements to operation products

General requirements **when submitting the tender**

Sykehusinnkjøp's Restricted Substances List at the time:

- The Candidate List (SVHCs)
- Pthalates on the Candidate List, the Restriction List and the SIN List
- Bisphenols
- PVC
- Antimicrobial agents
- Latex

Additional requirements:

- PFAS
- Allergenic substances Rosin (CAS 8050-09-7, 8052-10-6, 73138-82-6) and Lanolin (CAS 8006-54-0)

Exemptions to the general requirements, based on market dialogue:

- Products required to have (i) phased out substances on the Candidate List and Phtalathes **by contract start** and (i) award criteria on PVC with **40 % weighting (result: still in PVC)**
 - 28 Sugemunnstykker
 - 30 Sugesett
 - 31 Sugeslanger
 - 37 Merkepenn operasjon


Additional requirements for drapes

Award criteria on 20 % biobased material, top layer minimum 70% biobased, with 40 % weighting

Example of an environmental form

Product Name		Evaluering av miljøinformasjon i dokumentasjon til leveranser av miljøprodukter i henhold til...										Miljø		Sikkerhet		Dokumentasjon
Bredde	Høyde	1	2	3	4	5	6	7	8	9	10	11	12	13	14	
		Informasjon om miljøinformasjon i produktet i seg selv	Informasjon om miljøinformasjon i produktet i seg selv	Informasjon om miljøinformasjon i produktet i seg selv	Informasjon om miljøinformasjon i produktet i seg selv	Informasjon om miljøinformasjon i produktet i seg selv	Informasjon om miljøinformasjon i produktet i seg selv	Informasjon om miljøinformasjon i produktet i seg selv	Informasjon om miljøinformasjon i produktet i seg selv	Informasjon om miljøinformasjon i produktet i seg selv	Informasjon om miljøinformasjon i produktet i seg selv	Informasjon om miljøinformasjon i produktet i seg selv	Informasjon om miljøinformasjon i produktet i seg selv	Informasjon om miljøinformasjon i produktet i seg selv	Informasjon om miljøinformasjon i produktet i seg selv	
MHT-544	ACTIVITY GUARD MHT-544 PUMP 7XX EH	Y	Y	N/A	Y	Y	Y	N/A	Y	Y	Y, Polycarbonate/Kevlar/ABS	Y	H	N/A		
MHT-117	AG MHT-117 SHOWER PACK 3PK PUMP EH	Y	Y	N/A	Y	Y	Y	N/A	Y	Y	Y, Polyethylene	Y	H	N/A		
ACC-LRE	BATTERY ACC-LRE 4PK ULTR AA EH	Y	Y	N/A	Y	Y	Y	N/A	Y	Y	Y, Supplier Proprietary Information	Supplier Proprietary Information	H	N/A		
MHT-625EU	BATTERY MHT-625EU 4PK AAA 1.5 EOC	Y	Y	N/A	Y	Y	Y	N/A	Y	Y	Y, Supplier Proprietary Information	Supplier Proprietary Information	H	N/A		
ACC-258DE	BELT ACC-258DE PUMPWAIST BEIGE	Information is being concealed	Information is being concealed	N/A	Information is being concealed	Information is being concealed	Information is being concealed	N/A	Y	Y	Y, Nylon/Polyester	Y	H	N/A		
ACC-458	BELT ACC-458 SPIDELT PRDGH KIDS 1PK SF	Information is being concealed	Y	N/A	Y	Information is being concealed	Y	N/A	Y	Y	Y, Supplier Proprietary Information	Supplier Proprietary Information	H	N/A		
ACC-581DK	BELT ACC-581DK PUMP COMFY LRG BK	Information is being concealed	Y	N/A	Y	Information is being concealed	Y	N/A	Y	Y	Y, Supplier Proprietary Information	Supplier Proprietary Information	H	N/A		
ACC-1527	CAP ACC-1527 BTRY PUMP REPLACEMENT	Y	Y	N/A	Y	Y	Y	N/A	Y	Y	Y, PC/ABS	Y	H	N/A		
ACC-268	CASE ACC-268 PUMP DENIM BLUE	Information is being concealed	Y	N/A	Y	Information is being concealed	Y	N/A	Y	Y	Y, Nylon/Polyester/Polyester/Polyethylene	Y	H	N/A		
ACC-388PL	CASE ACC-388PL PUMP SPORTS BLUE	Information is being concealed	Y	N/A	Y	Information is being concealed	Y	N/A	Y	Y	Y, Nylon/Polyester/Polyester/Polyethylene	Y	H	N/A		
ACC-318DK	Case ACC-318DK Pump Fly Leather DK EH	Information is being concealed	Information is being concealed	N/A	Information is being concealed	Information is being concealed	Information is being concealed	N/A	Y	Y	Y, Supplier Proprietary Information	Supplier Proprietary Information	H	N/A		
ACC-883DK	CASE ACC-883DK PUMP LEATHER MALE BLACK	Information is being concealed	Y	N/A	Y	Information is being concealed	Y	N/A	Y	Y	Y, Valsal	Y	H	N/A		
ACC-818DK	CASE ACC-818DK PUMP NEOPRENE BLACK	Information is being concealed	Y	N/A	Y	Information is being concealed	Y	N/A	Y	Y	Y, Neoprene/Nylon/Rubber	Y	H	N/A		
ACC-822DK	CASE ACC-822DK PUMP NGR 3.BML DLX EH	Information is being concealed	Y	N/A	Y	Information is being concealed	Y	N/A	Y	Y	Y, Silicone	Y	H	N/A		
ACC-822DK	CASE ACC-822DK PUMP NGR 3.BML DLX EH	Information is being concealed	Y	N/A	Y	Information is being concealed	Y	N/A	Y	Y	Y, Silicone	Y	H	N/A		
ACC-851PL	CASE ACC-851PL PUMP LENHY 3.BML PURPLE	Information is being concealed	Information is being concealed	N/A	Information is being concealed	Information is being concealed	Information is being concealed	N/A	Y	Y	Y, Supplier Proprietary Information	Supplier Proprietary Information	H	N/A		
ACC-851PL	CASE, SILICON, KIDS LENHY 3.OHL, BLUE	Information is being concealed	Information is being concealed	N/A	Information is being concealed	Information is being concealed	Information is being concealed	N/A	Y	Y	Y, Supplier Proprietary Information	Supplier Proprietary Information	H	N/A		
ACC-851OR	CASE, SILICON, LENHY KIDS 3.OHL, ORANGE	Information is being concealed	Information is being concealed	N/A	Information is being concealed	Information is being concealed	Information is being concealed	N/A	Y	Y	Y, Supplier Proprietary Information	Supplier Proprietary Information	H	N/A		
ACC-1581	CLIP ACC-1581 PUMP NGR 23L	Y	Y	N/A	Y	Y	Y	N/A	Y	Y	Y, PC	Y	H	N/A		
ACC-845	HARNESS ACC-845 PUMP CHILD RD/PK EH	Information is being concealed	Information is being concealed	N/A	Information is being concealed	Information is being concealed	Information is being concealed	N/A	Y	Y	Y, Supplier Proprietary Information	Supplier Proprietary Information	H	N/A		
ACC-845PL	HARNESS ACC-845PL PUMP TODDLER BLEH	Information is being concealed	Information is being concealed	N/A	Information is being concealed	Information is being concealed	Information is being concealed	N/A	Y	Y	Y, Supplier Proprietary Information	Supplier Proprietary Information	H	N/A		
MHT-647CI	MOUSE MHT-647CI PUMP DRDGH 3YY	Y	Y	N/A	Y	Y	Y	N/A	Y	Y	Y, Polycarbonate/ABS	Y	H	N/A		

Exemptions when there is a medical reason (i.e. desired, not because of lack of alternatives on the market)



Health Care Without Harm Europe

European healthcare's phase-out list for chemicals of concern

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² The MDR: eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32017R0745
 Endocrine-disrupting substances in the MDR are covered by the Candidate List and the restricted Phthalates.
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⁴ ChemSec SIN List: sinlist.chemsec.org

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Flame retardants – All articles or component articles of a complex article do not contain flame retardants, unless specifically requested.

Antibacterial agents – All articles or component articles of a complex article do not contain antibacterial agents, unless specifically requested.

Perfluoroalkyl substances (PFAS)⁵ – All articles or component articles of a complex article do not contain stain- or water-repellent substances that contain total PFAS over 0.1% (w/w).

⁵ PFAS, as defined by the OECD: [oecd.org/officialdocuments/publicdisplaydocumentpdf/?cote=ENV/CBC/MONO\(2021\)25&docId=11642421](https://www.oecd.org/officialdocuments/publicdisplaydocumentpdf/?cote=ENV/CBC/MONO(2021)25&docId=11642421)

- Antibacterial agents
 - Antibacterial suturs (triclosan)
 - Antibacterial wound dressing (nanosilver)
- Latex gloves, when requested
- Flame retardency in furniture/curtains etc. in psychosomatic unit

Environmental concerns and opportunities

- Quantity in use
- Limitations to recycling (hazardous waste / complex products)
- Extend range of ecolabeled products
- Ensure adaptation of European healthcare's phase-out list to maintain current wins and increase product availability
- Product database / product passport with ingredients