Medical devices

Subject of procurement
Respirators, ventilators, dialysis equipment, diathermy machines, defibrillators, infusion pumps, surgical microscopes, patient monitoring equipment, operating tables, mechanical and electric hospital beds, hospital bassinets and paediatric hospital beds, IV poles, geriatric chairs, hygiene, research and transport and first aid fixtures **Key impacts** • The carbon dioxide and other emissions created in the energy production and use during the product's whole lifespan • Reduction of non-renewable natural resources as the result of raw material utilisation and use of oil/natural gas needed in manufacture • Contamination of air, soil, and water, tropospheric ozone formation and accumulation of harmful substances in living organisms due to harmful substances contained in the materials • Waste from production and packaging • The use of child labour, violations to workers' rights, forced labour, and other human rights issues in the production chains of certain products in particular.

Aims	Guiding documents
• Reduction of chemicals and harmful substances • Reduction of PVC • Reduction of waste, and recycling • Reduction of other environmental effects • The consideration of social responsibility	The proposed requirements for the procurement and comparison criteria, as presented below, are based on these documents. • Medical Devices Act (629/2010) • IEC 60601-1-9 – Environmentally Conscience Design for Medical Equipment • Ministry of Economic Affairs and Employment 2015: Energy efficiency in awarding public contracts (PDF only in Finnish) • EU Training Toolkit GPP 2014: Green Public Procurement Criteria for Electrical and Electronic Equipment used in the Health Care Sector • Candidate List of substances of very high concern for Authorisation • Finnwatch (2019): Code of Conduct – Minimum sustainability requirements and supply chain management • ILO: Ratifications by country

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Incorporating sustainability and responsibility into the procurement

The guiding documents offer good examples of how to incorporate sustainability and responsibility into the procurement. Aspects related to sustainability and responsibility can, therefore, be included in the procurement by

choosing among the options listed below. It is important to take into consideration that market conditions, subjects of procurement, and circumstances may vary in different regions. The procurement unit shall always check and set the level of criteria based on its own goals and market analysis. To achieve the goals set for the procurement, other requirements, comparison criteria, and agreement terms can be specified.

Safety

Requirement	Verification
Basic level	
Traceability: The product can be traced.	Account specifying the country of manufacture of the product.
Harmful substances: The tenderer shall deliver an account of any substances that have been classified as belonging to the Candidate List of substances of very high concern for Authorisation based on the REACH Regulation (1907/2006) that [Product(s) in question] contain(s). The account shall cover any substances that contain more than 0.1 weight percent/substance in each individual component of the product. If any of the substances the product contains are added to the Candidate List during the agreement period, the supplier shall inform the orderer of this within six months after the Candidate List update has been published. Candidate List of substances of very high concern for Authorisation *Note: To verify the criterion, it is important to also consider how the supplier meets the requirements related to the information management on harmful substances. See also the requirement entitled 'Information management on harmful substances'.*	The tenderer declares they meet the requirement (yes/no). The tenderer shall be able to produce a document proving the requirement is met upon request.
Information management on harmful substances: The tenderer shall have procedures in place for handling and monitoring information related to any substances the products tendered contain that are harmful to the environment and health. The procedures shall ensure there is information available on any substances whose concentration is more than 0.1 weight percent. The following substances are	The tenderer declares they meet the requirement (yes/no). The tenderer shall be able to produce a document proving the requirement is met upon request. The requirement can be verified with the ISO 13485:2016 standard.

Requirement	Verification
under scrutiny here: - The Candidate List of substances of very high concern for Authorisation of the REACH Regulation (Article 59; EC 1907/2006; Regulation concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals) - Annex XVII (Restrictions on the manufacture, placing on the market and use of certain dangerous substances, mixtures and articles) to REACH (EC 1907/2006) - Annex II to the RoHS Directive (Directive 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment)	
Advanced level	
Traceability: The product's whole supply chain has been described all the way down to the ingredients.	The tenderer declares they meet the requirement (yes/no). The supplier shall deliver an account of the whole supply chain containing information on all the manufacturing plants involved in the manufacturing of the product upon request.
Phthalates: Products and related supplies shall not contain more than 0.1 weight percent/substance of phthalates (esters of 1,2-benzenedicarboxylic acid) included on the Candidate List of substances of very high concern for Authorisation of the REACH Regulation in any individual component of the product. Annex 1 includes the list of phthalates that are on the Candidate List of substances of very high concern for Authorisation as of May 2019. Candidate List of substances of very high concern for Authorisation *Note: New restrictions on health care devices will enter into force on 22 July 2021. The following phthalates will be added to the list of restricted substances of RoHS legislation:* • *bis(2-ethylhexyl) phthalate, DEHP* • *benzyl butyl phthalate, BBP* • *dibutyl phthalate, DBP*	The tenderer declares they meet the requirement (yes/no). The tenderer shall be able to produce a product description or another document proving the requirement is met upon request.

Requirement	Verification
• *diisobutyl phthalate, DIBP.*	
Bisphenol A in a dialysis machine: The membranes, filters and tubing of the machine shall not contain bisphenol A (CAS No. 80-05-7).	The tenderer declares they meet the requirement (yes/no). The tenderer shall be able to produce a product description or another document proving the requirement is met upon request.

Environmental responsibility

Requirement	Verification
Basic level	
Warranty period: The warranty period of the device shall be at least [X] years. *Note: The minimum length of the warranty period shall be determined device-specifically by means of a market survey.* *The procurement unit shall also specify what the warranty shall cover at minimum.*	The supplier shall provide a written warranty and a description of the content of the warranty to the orderer.
Ecodesign: The device meets the requirements regarding environmentally conscience design of medical equipment of the IEC 60601-1 standard (IEC 60601-1-9), based on the EuP Directive. *Note: The requirement shall take into account transition periods of device manufacturing, which can be long.*	IEC 60601-1-standardised devices meet the requirements. Other appropriate account by the tenderer demonstrating compliance with the requirements of the standard shall also be accepted.
Training to optimise energy efficiency when installing the device: The tenderer shall provide training for energy-efficiency optimisation and describe the installation procedure and the adjustments of the device to ensure energy-efficient use.	The tenderer declares they meet the requirement (yes/no). Upon request, the tenderer shall provide a description of training to be given at the time of the installation procedure.
Packaging: The transport packaging of the product shall be made out of recycled and/or renewable	The tenderer declares they meet the requirement (yes/no).

Requirement	Verification
materials or it shall be multiple-use or recyclable.	The tenderer shall be able to produce a document proving the requirement is met upon request.
Warranty clauses: Contractual clause: The repair or replacement of the product shall be included in the manufacturer's warranty clauses.	
Warranty clauses: Contractual clause: The tenderer shall ensure the availability of spare parts for a period of [XX] years after the manufacture of the device has ended. *Note: The procurement unit shall determine [XX] shares product group-specifically by means of a market dialogue.*	
Recycling: Contractual clause: The supplier is responsible for taking the transport packaging materials for reuse, recycling or to an appropriate waste collection point.	
Advanced level	
Warranty period: The tender will receive an additional point if the warranty period for the tendered device exceeds the minimum requirement. *Note: See the basic level requirement for the warranty period.* *The procurement unit shall also specify, together with the tenderer/supplier, what the warranty covers. It is good to take into consideration that if the warranty period of the device is longer than at the basic level, the supplier may require a commitment to, for example, scheduled maintenance.*	The supplier shall provide a written warranty and a description of the content of the warranty to the orderer.
Consumption of working fluid/gas: (For example, dialysate, inhalational anaesthetic) The device has an automatic working fluid/gas reduction system.	The tenderer declares they meet the requirement (yes/no). The tenderer shall produce a document proving the requirement is met upon request.
Instructions for use: The device shall be delivered with Finnish or English instructions for use, including instructions for maximising the energy efficiency of the device. The manual shall be available together with the device and include at least the following information:	The tenderer declares they meet the requirement (yes/no). The tenderer shall produce a document proving the

Requirement	Verification
• Information on ways of using the device to reduce electricity consumption • Instructions and recommendations for product maintenance, including cleaning instructions and information on which spare parts can be replaced. The manual shall also be available in electronic format. *Note: The contents and availability of the instructions for use shall be ensured by means of a market dialogue device-specifically.*	requirement is met upon request.

Social responsibility

Requirement	Verification
Basic level	
Managing the supply chain and social responsibility: *Note: The guide includes a sample of the Code of Conduct version (10/2019) used by HUS. What this agreement term covers is determined on the basis of the individual product group/product/agreement.* Example of an agreement term: 1. The minimum requirements of the Code of Conduct: The supplier shall actively ensure the products covered by this [agreement/framework agreement] are manufactured in conditions that are in compliance with the minimum requirements of the Code of Conduct listed in Annex [number]. The supplier is responsible for monitoring the supply chain and taking appropriate action to ensure the minimum requirements of the Code of Conduct are met in their own operations, as well as in the supply chain of the products and services covered by the framework agreement. By signing the agreement, the supplier agrees to the minimum requirements of the Code of Conduct as listed in the annex of the agreement, as well as to ensure these minimum requirements are met in their own operations and supply chain. The supplier shall assist [the procurement unit] in the following of the framework agreement, for example by delivering [the procurement unit] reports and accounts detailing the ways they have fulfilled the obligations laid out in section 1. The report or account shall be delivered within six (6) weeks of [the procurement unit] making the request. *Sanctions* If the supplier violates the minimum requirements of the Code of Conduct as laid out in section 1 of the social responsibilities, [*the procurement unit*] is entitled to take the following actions due to the violation: I. Reparative actions: [The procurement unit] has the right to ask the supplier in writing to produce a plan and timetable to perform reparative actions to meet the obligations laid out in section 1 for the approval of [*the procurement unit*] within [amount of] months or in a time frame specified by [the procurement unit]. The proposed actions and timetable shall be proportionate to the gravity of the violation, and the plan shall clearly state the concrete ways in which the supplier intends to correct the violation in the time frame given. II. Compensations: If the supplier does not commit to the aforementioned approved plan and timetable, fails to deliver them, or fails to finish the agreed-upon tasks in the time allotted, [the procurement unit] is entitled to demand compensation from the supplier: a thousand (1,000) euros for each starting seven-day (7) delay period, but no more than 15,000 euros in total. III. Restricting client-specific agreements and orders: Besides demanding reparative actions, [the procurement unit] may limit the supplier's right to participate in such competitive tendering of the clients as falls outside the scope of the Act on Public Procurement and Concession Contracts and/or reduce the clients' orders from the supplier as covered by the framework contract until the supplier has corrected the violation to the minimum requirements of the Code of Conduct as laid out in section 1, or when it is obvious the violation has ended. IV. Termination of the agreement: [The procurement unit] has the right to terminate the agreement	

Requirement	Verification
immediately either completely or in parts if the supplier fails to perform the reparative actions as laid out above and the abovementioned compensation owed has reached the maximum limit. The client may terminate the client-specific agreement immediately either in full or partially, if the minimum requirements of the Code of Conduct as laid out in section 1 have been violated in the production of the products covered by it and the supplier has failed to perform the abovementioned reparative actions.	
Advanced level	
Managing the supply chain and social responsibility: 2. Actions and policies The supplier shall perform the following tasks no later than at the beginning of the agreement period, or at a later date specifically agreed upon with [the procurement unit]; for the sake of clarity, it shall be stated that the following policies and actions can be written in a language of the supplier's choosing (e.g. in English): I. The supplier shall write, approve, and publish one or more policies approved by the management that includes a commitment to follow the minimum requirements of the Code of Conduct mentioned in section 1; II. The supplier shall communicate this policy to their own supply chain with whom they have a contractual relation; III. The supplier shall appoint a management-level person in charge to make sure the minimum requirements of the Code of Conduct mentioned in section 1 are being observed; IV. The supplier shall have a process in place to perform regular risk assessments, including identifying and prioritising the monitoring of any existing or potential risks associated with the following of the minimum requirements of the Code of Conduct mentioned in section 1; V. The supplier shall have a process in place to constantly ensure its operations are compatible with the minimum requirements of the Code of Conduct mentioned in section 1; VI. The supplier shall have a process in place to prevent any issues and aberrations from the minimum requirements of the Code of Conduct mentioned in section 1 and immediately reduce and remove their harmful impact, for example by fixing the issue or aberration in question. The aforementioned actions shall be documented, and they shall be followed constantly. These actions shall be followed in the supplier's own operations and the whole supply chain. The supplier shall assist [the procurement unit] in the following of the framework agreement, for example by delivering [the procurement unit] reports and accounts detailing the ways they have fulfilled the obligations laid out in section 2. The report or account shall be delivered within six (6) weeks of [the procurement unit] making the request. *Note: It is recommended the procurement unit requires its contractual partner to follow not only the basic-level section 1 but also the actions and policies related to responsibility in accordance with section 2, 'Actions and policies'.* ——————————————————————————————————————— Auditing right *3.* The supplier shall allow [the procurement unit] or its representative reasonable access to any relevant information, as well as reasonable access to the supplier's facilities as is necessary for [the procurement unit] to be able to make sure the supplier's operations are run in accordance with their obligations as laid out in	

Requirement	Verification
sections 1 and 2. Auditing rights, notice about auditing and its deadlines, procedures, confidentiality, and the right to audit the operations of subcontractors are discussed further in section [XX] [Inspection right]. If the manufacturer of the products is a business in the supply chain other than the supplier's subcontractor, the supplier shall cooperate as much as possible with [the procurement unit] so it is able to audit also the operations of the manufacturing plant of any such business in the supply chain. 4. The supplier shall be able to tell [the procurement unit] which manufacturing plant the individualised replacement product comes from upon request. *Note: It is recommended the procurement unit reserves the right to audit manufacturing plants. It is also important for the procurement unit to make sure it has enough resources during the agreement period to follow and monitor the truthfulness of claims of responsibility.* _____ Sanctions If the supplier violates the minimum requirements of the Code of Conduct as laid out in section 1 of the social responsibilities or neglects to perform the actions agreed upon in section 2, [*the procurement unit*] is entitled to take the following actions due to the violation: I. Reparative actions: [The procurement unit] has the right to ask the supplier in writing to produce a plan and timetable to perform reparative actions to meet the obligations laid out in sections 1 and 2 for the approval of [*the procurement unit*] within [amount of] months or in a time frame specified by [the procurement unit]. The proposed actions and timetable shall be proportionate to the gravity of the violation, and the plan shall clearly state the concrete ways in which the supplier intends to correct the violation in the time frame given. II. Compensations: If the supplier does not commit to the aforementioned approved plan and timetable, fails to deliver them, or fails to finish the agreed-upon tasks in the time allotted, [the procurement unit] is entitled to demand compensation from the supplier: a thousand (1,000) euros for each starting seven-day (7) delay period, but no more than 15,000 euros in total. III. Restricting client-specific agreements and orders: Besides demanding reparative actions, [the procurement unit] may limit the supplier's right to participate in such competitive tendering of the clients as falls outside the scope of the Act on Public Procurement and Concession Contracts and/or reduce the clients' orders from the supplier as covered by the framework contract until the supplier has corrected the violation to the minimum requirements of the Code of Conduct as laid out in section 1, or when it is obvious the violation has ended. IV. Termination of the agreement: [The procurement unit] has the right to terminate the agreement immediately either completely or in parts if the supplier fails to perform the reparative actions as laid out above and the abovementioned compensation owed has reached the maximum limit. The client may terminate the client-specific agreement immediately either in full or partially, if the minimum requirements of the Code of Conduct as laid out in section 1 have been violated in the production of the products covered by it and the supplier has failed to perform the abovementioned reparative actions.	
Managing the supply chain, auditing report: Example of an agreement term/obligation: If the industrial manufacturing of the contract products	The tenderer declares they meet the requirement (yes/no).

Requirement	Verification
takes place in a country that has not ratified the ILO's environmental, social and labour law obligations referred to in in Point 5 of Subsection 1 of Section 81 of the Act on Public Procurement and Concession Contracts, the supplier shall be prepared to deliver the latest auditing report of the manufacturing plant to [the procurement unit]. An acceptable auditing report is an audit on social responsibility (e.g. BSCI, SA8000, or a similar audit) performed by an objective third party that the manufacturing plant in the risk country has passed. The orderer is also to be given the opportunity to audit or to use a partner to audit the supplier or their subcontractors at any point during the agreement period. If the manufacturing plant changes during the agreement period, as per the requirements of the call for tenders, the chosen supplier shall present the exact name and address and/or GPS coordinates of the new manufacturing plant, as well as the latest auditing report from the plant that the plant has passed, which can be done as the aforementioned audit on social responsibility performed by a third party.	The supplier shall deliver the required documentation on passing the objective third-party social responsibility audit on manufacturing plants in risk countries upon request. The term 'risk country' refers to a country that has not ratified the ILO's environmental, social and labour law obligations.

Annex 1 Phthalates

	Substance	CAS number
1	Bis(2-ethylhexyl) phthalate (DEHP)	117-81-7
2	Bis(2-methoxyethyl) phthalate; Di(2-methoxyethyl) phthalate (BMEP; DMEP)	117-82-8
3	Dipentyl phthalate (DPP)	131-18-0
4	Diisopentyl phthalate (DIPP)	605-50-5
5	1,2-benzenedicarboxylic acid, di-C7-11-branched and linear alkyl esters (DHNUP)	68515-42-4
6	Di-C6-8-branched alkyl phthalates (DIHP)	71888-89-6
7	N-Pentyl-isopentyl phthalate	776297-69-9
8	Diisobutyl phthalate (DIBP)	84-69-5
9	Dibutyl phthalate (DBP)	84-74-2
10	Dihexyl phthalate (DnHP)	84-75-3
11	1,2-benzenedicarboxylic acid, dipentyl ester, branched and linear	84777-06-0
12	Benzyl butyl phthalate (BBP)	85-68-7
13	1,2-benzenedicarboxylic acid, dihexyl ester, branched and linear	68515-50-4
14	Hexyl octyl decyl phthalate	68515-51-5
15	1,2-benzenedicarboxylic acid, di-C6-10-alkyl esters or mixed decyl and hexyl and octyl diesters	68648-93-1
16	Diisononyl phthalate (DINP)	28553-12-0 and 68515-48-0
17	Diisodecyl phthalate (DIDP)	26761-40-0 and 68515-49-1
18	Di-n-octyl phthalate (DNOP)	117-84-0