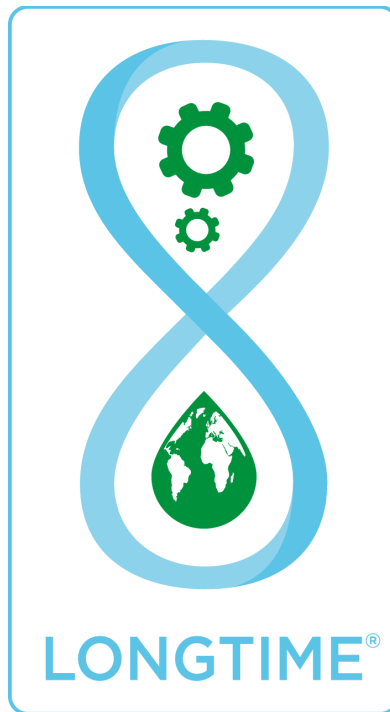




Certification PSR

STRETCHERS AND MEDICAL CHAIRS V1.6

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I. INTRODUCTION

Drawing on the standards of the NF EN 45550 series, and in line with NF EN 45552 and NF EN 45554, the LONGTIME® sector-specific standards specify requirements relating to the assessment of robustness, reliability and repairability for the associated product family.

All qualitative, semi-quantitative and quantitative data are derived from a research and consultation process, as required by the applicable standards, and take into account bibliographic references (scientific studies, regulations, standards, etc.) as well as input from all relevant stakeholders, namely: economic operators placing products on the market (manufacturers, importers and distributors), their suppliers and/or subcontractors, product experts (repairers, installers and professional testers), spare parts professionals, refurbishers, consumers, consumer associations, environmental organisations, and any other stakeholders able to contribute relevant added value, subject to the availability of networks and information.

The definition of prerequisites relating to quality, energy thresholds, pollutant emission thresholds, the classification of parts, and the definition of thresholds for accessibility scales are based on the analysis of the consultations conducted and on consideration of the best available ecodesign practices on the market.

Vision of LONGTIME®

This project is part of a dynamic of societal movement with the desire to move ahead of regulations. This label is made by citizens, for citizens. It provides certainty that the product carrying the label is manufactured for long-term use, as desired by 80% of consumers, and that it is economically repairable.

LONGTIME® is a simple, strong and effective tool, created to inform the consumer actor concerned about the overall impact of their purchases, but also the consumer wishing to acquire a product with a fair longevity/price ratio. It also tends to bring to the forefront manufacturers keen to offer products with an optimized lifespan.

Label objectives

This approach involves encouraging different consumption, therefore aiming to produce differently. Almost all citizens want a transformation of the consumer society with a real change in the technical-economic paradigm in order to consume better and more sustainably.

The ecological interest is of course major, on a global scale we have increased our consumption of raw materials in just a few decades to now exceed 60 billion tonnes per year. The label influences the preservation of planetary resources, through better use of them and the reduction of waste.

Intuitively, therefore, obtaining a good with an optimized lifespan promotes reasoned use of our planet's resources, reduces overconsumption and allows us to move away from disposable

items and waste. It is not a question of looking for “immortal” products but of fighting against the too short lifespan of products.

Extending the service life of stretchers and medical chairs by several years may reduce life cycle impact category indicator results for categories predominantly driven by production stages upstream of the use phase.

For other impact categories, the environmental benefit of service life extension will depend largely on the energy efficiency of the replacement product, given that the average service life of stretchers and medical chairs is estimated at 10 years.

Consequently, replacing such a product before the end of this estimated 10-year service life may be environmentally beneficial under certain conditions, particularly where the replacement product offers a significant improvement in energy efficiency.

Fields of application

The label is applicable to different product families as long as there is an assembly of parts. LONGTIME® tends to cover domestic, electronic, portable power appliances, furniture, leisure equipment, professional equipment, etc. The range of products is therefore very vast but excludes automobiles, textile products (excluding leather goods), food, cosmetics and chemicals.

Organization of the certification PSR

The criteria are broken down into several categories and the presentation of the criteria follows the following diagram:

Criteria category

The criteria are grouped into 11 main categories

Criterion number and name

Each criterion has an identification number in I.X.X format and a name allowing its theme to be defined.

Requirement level (KO/Major/Minor)

See table below

TRANSVERSE CRITERION

Criterion applicable to all product categories

❖ Spécification ou Product Specific Requirement (PSR)

Specific criterion whose scope is adapted to the product category of the framework.

Means of proof

Details of the means of proof required and/or relevant for the evaluation of the criterion and its PSRs

A level of requirement is assigned to each label criterion according to the classification indicated in the table below:

KO	These criteria must be respected to qualify for labeling after the initial audit (year N).
Major	These criteria must be respected at least 80% during the audit. They will lead to the implementation of corrective actions to reach 100% by year N+1.
Minor	These criteria must be respected at least 50% during the audit. They will lead to the implementation of corrective actions to reach 80% by year N+1 and 100% by year N+2.

Control system

The assessment of compliance with the benchmark criteria is carried out by an approved and independent inspection body.

Each criterion is assessed using a compliant/non-compliant approach

More details on the control system in the labeling process available on the [LONGTIME® labeling conditions online](#).

Standards and regulations

The standards or regulations cited in the reference system use the most recent versions and/or equivalences published in the official journal of the European Union.

II. DEFINITION OF THE PRODUCT SCOPE

The “Stretchers and Medical Chairs” standard covers two main product families:

Medical chairs are freestanding or mobile seating devices designed to provide seating suited to patients’ needs in a medical setting. They generally incorporate specific features, such as adjustable armrests, removable footrests, backrest recline or seat height adjustment. These functions may be operated manually or by electrically, hydraulically or pneumatically powered mechanisms.

Medical stretchers are mobile patient support devices used to transport patients within healthcare facilities or during emergency transfers. Stretchers are designed to be robust and readily manoeuvrable, incorporating locking mechanisms to ensure patient safety. They are often height-adjustable and fitted with mattresses to provide patient comfort during transport.

Product scope

- Medical recliner chair
- Powered wheelchair
- Manual wheelchair
- Standard transport stretcher
- Battery-powered stretcher
- Mains-powered stretcher
- Electrically operated stretcher
- Hydraulically operated stretcher
- Pneumatically operated stretcher

Outside the product scope

- Shower chair or transfer chair
- Special-purpose stretcher (gynaecology, etc.)
- Examination couch
- Domestic indoor/outdoor armchair
- Massage chair
- Massage table
- Domestic furniture
- Medical bed

III. TERMS AND DEFINITIONS

Depending on sectoral standards, definitions specific to different product categories (parts, functions, etc.) can be added to the recurring definitions below.

AMDEC / FMEA

Tools allowing the Analysis of Failure Modes, their Effects and their Criticality / Failure Mode and Effect Analysis.

Permanent assembly

It is a set of components forming a single piece or part of a product and cannot be dismantled without destruction or alteration of the use for which it is intended.

To remove the connection between two assemblies or parts, it is necessary to deform, degrade or destroy at least one of the parts forming the assembly. Examples: welding, crimping, clinching, stamping, bonding and adhesives.

Constraint of use

It corresponds to the forces which apply to the part.

Criticality

The criticality of a failure refers to the importance or impact of this failure on the proper functioning of a product. It is evaluated according to the severity of the consequences that the failure could cause, particularly in terms of safety/costs, and the frequency of occurrence.

Actual failure

Failure which is actually linked to a malfunction of the product and not to an exogenous problem. (e.g. power outlet not powered, power cable not properly connected, lid not properly locked, etc.)

Expected lifespan

Period during which the user expects their product to perform as intended.

Seasonal energy efficiency for space heating

The ratio (N_s), expressed as a %, between the space heating demand for a designated heating season, covered by a heating device, and the annual energy consumption required to meet this demand.

Household appliances

Product powered by electrical energy and intended for domestic use only.

Compostable packaging

Container designed with materials capable of decomposing naturally under the action of microorganisms present in the composter to become a natural or organic element of the substrate.

Reusable packaging

Container designed to be used multiple times, reducing the need for disposable packaging.

Non-recoverable packaging

Refers to a type of packaging that cannot be effectively recovered, recycled or reused after use.

Regular maintenance

Maintenance recommended by the manufacturer to keep the product in optimal operating condition.

Working environment

When resolving failure scenarios, several working environments may be listed.

EOS

Acronym for Electrical Overstress reflecting a state of undesirable electrical overload likely to lead to damage or failure of the product.

Step (disassembly)

Operation leading to the removal of a part or a tool change.

Reusable attachment

Corresponds to an original fixing system removed during disassembly without altering the product and which is reusable during reassembly (e.g. screws, clips).

Removable attachment

Corresponds to an original fixing system which can be removed during disassembly without altering the product, but which cannot be reused during reassembly (e.g. plastic clamp, rivet).

HS

Out of service ; corresponds to exiting the functional state.

Spare parts interface

Refers to how parts connect or integrate with existing components of a product. Depending on the type of part and the type of interface used to connect them, a classification is established: A standard part is a component, a part, manufactured according to recognized specifications and standards, commonly used and compatible with various products or systems.

IOT

Internet of Things or internet of objects; This function corresponds to the fact of being able to connect your product to the internet in order to obtain additional remote control and/or regulation functionalities.

Competence level

Resolving a failure scenario may require skills such as the ability to identify and locate the failure, access the affected area in the product, handle appropriate tools, and manage any risks related to the product, environment, and environment. the operator. Depending on the level of technical skill necessary to carry out the repair, several levels are defined:

Non usage

It corresponds to a non-operating state of the device.

O.S

Operating System, or operating system, is a set of programs that direct the use of a computer's resources by application software.

“General public” tools

Common tools, for general use, available to the general public in traditional distribution and as specified in the EN 45554 standard tools list: screwdriver (slotted head screw, cruciform, 6 internal lobes, wrench (hexagon socket screw, mixed), pliers (universal, half-round nose, diagonal cutting, power strip, vice, for stripping and crimping terminals), pry bar, tweezers, hammer with steel head, utility knife (cutting pliers with retractable blade), multimeter, voltage tester , soldering iron, glue gun, magnifying glass.

“Experienced Audience” tools

Tools requiring skills to use and whose cost can represent a barrier (torque wrench, soldering iron, etc.).

“Professional” tools

Tools requiring specific knowledge or conditions of use and whose acquisition cost represents an investment.

Proprietary tool

Specific tool, not commercially available, belonging exclusively to a party or a company, and by virtue of which, its use by another party (end user, customer, repairer) implies copyright, a license and/or a cost.

External source parts

Parts external to the manufacturer's production body, coming from an identified supplier.

Unit cost price “PRU” of a product/part

Understood as the sum of the price of the parts making up a product/components of a part.

“Great utility” product

A very frequently used product which, in the event of a breakdown, causes a significant disruption in day-to-day management: refrigerator, washing machine, boiler/water heater, telephone, computer, hob, etc.

Disassembly depth

Corresponds to the sum of the steps allowing individual access to each part and detaching it from the equipment, with a view to its replacement.

Data management process

Refers to all the practices and procedures put in place by an organization to collect, store, process, protect, and manage the personal information of individuals using their products.

PSR

“Product Specific Requirement” corresponds to the criterion specifications applicable to the types of equipment specified within the scope of the framework.

Serialization

Practice by which the producer limits the use of spare parts to only original parts that he approves, in particular by software means.

Example: associate the serial numbers of the components of a product with the overall serial number of the product.

Subset

Set of connected components inseparable from each other which form a block and provide a function. The subassembly can be separated from the product.

Example: Motor and welded electronic card

Disruptive technology

Technology whose operation brings an innovation or a major technological advance compared to previous ones and whose reliability has not yet been fully proven over time.

IV. NOMENCLATURE OF PARTS

List of parts representative of the target product group but not-exhaustive.

- **Medical furniture body assembly**
 - Mobile base frame
 - Control panel
 - Housing, covers and cladding panels (front/rear, side, top/bottom)
 - Patient support platform frame
 - Push handle
 - Bumper system
 - Accessory holders (for cylinders, IV poles, etc.)
 - Headrest
 - Wrist support
 - Footrest
 - Side rails
- **Control assembly (start-up, adjustments, programmes, etc.)**
 - Control buttons/handles (touch-operated, mechanical)
 - Remote control
 - Remote control cable
 - Control pedals for the various lifting/tilting mechanisms
- **Height adjustment, tilt and mechanical actuation assembly**
 - Shaft or torque transmission system (direct or indirect)
 - Bearings
 - Raising/lowering mechanisms
 - Pneumatic actuator
 - Hydraulic actuator
 - Electric linear actuator
- **Electrical and electronic assembly**
 - Power circuit boards
 - Control circuit boards
 - Electronic control module
 - Electronic display module

- › Analogue or digital display
- › Electric motor capacitor (start capacitor, run capacitor)
- › Thermal fuses (electric motor, drive mechanism, etc.)
- › Position or safety sensor/switch (Hall-effect sensor, microswitch, etc.)
- › Electronic locking system (switch, position switch)
- › Torque limiter
- › Batteries
- › LEDs/screens/visual mode indicators
- › Power supply cable
- › Ribbon cables
- › Interference suppression coil
- › Relays
- › Connectors and sockets

- › **Electric motor assembly**
 - › Rotor
 - › Stator
 - › End shield
 - › Gearbox
 - › Bearing
 - › Ball screw: tube, sleeve, washers
 - › Drive nut
 - › Motor shaft

- › **Wheel and mobility system assembly**
 - › Swivel castors
 - › Lockable castors
 - › Wheel treads
 - › Brake and steering pedals
 - › Steering system with central castor and integrated electric motor

- › **Mechanical joint sealing and stabilisation assembly**
 - › Sealing components (O-rings, sealing rings, lip seals, silicone seals, etc.)
 - › Fastening components (screws, bolts, circlips, washers, etc.)
 - › Stabilising components (springs, spacers, brackets, bearing supports, etc.)
 - › Linear motion mechanisms (slide rails)

- › **Upholstery assembly**
 - › Mattress
 - › Upholstery/seat
 - › Accessories
 - › Arm support
 - › Cushion
 - › Trays (general-purpose/meal/bottle holder/patient tray)

- › Stirrups
- › Paper roll dispenser
- › X-ray cassette holder
- › Transport straps
- › Side rail covers
- › Headboard and footboard
- › Rods
- › Reading light
- › Weighing scale
- › Surgical accessory rail
- › Safety belts

V. ACCESSIBILITY SCALE

The accessibility scale has 3 levels and aggregates data related to repairability; notably :

- › The dismantling depth of the part in number of steps
- › Dismantling time in minutes
- › The level of skill required to complete the task
- › The tools needed for the process

A	≤ 3 steps ≤ 10 mins any user consumer tools
B	≤ 10 steps ≤ 15 mins experienced user or repairer general public tools, experienced public tools
C	≤ 15 steps ≤ 20 mins experienced user or repairer general public tools, experienced public tools, professional tools

The scales indicated in the table above are orders of magnitude not to be exceeded but these thresholds can be limited more precisely in the criteria calling for accessibility scales.

If all the relevant safety instructions are followed, the dismantling process starts when the product is connected to the gas cylinder.

VI. PRODUCT EXPOSURE TO EXOGENOUS FAILURES

Definition

An exogenous failure of a manufactured product refers to a fault or malfunction arising from external factors or conditions beyond the control of the manufacturer or producer. Unlike an endogenous failure, which stems from internal design, manufacturing or quality issues, an exogenous failure generally results from unforeseen or unexpected external circumstances. For example, an exogenous failure of a manufactured product may be caused by factors such as extreme environmental conditions, transport accidents during delivery, improper handling by the end user, changes in government regulations, etc.

Managing exogenous failures in product manufacturing may involve implementing quality control measures, rigorous testing, supply chain management, warranties and return policies to address problems arising from these external factors.

Exogenous failure criteria

User risk:

Reflects the ability to respect conditions of use in the face of the weight of the constraints of use.

Associated levels:

- **Low:** the user scrupulously respects the product's rules of use, particularly for quality and safety reasons.
- **Medium:** the user generally respects the product's rules of use
- **High:** the user rarely respects the product's rules of use

Product handling:

Reflects the possibility of false handling, shocks, falls.

Associated levels :

- **Low:** Not handled
- **Medium:** Handling without moving or dismantling
- **High:** Handling with moving or dismantling

Weather exposure:

Refers to exposure to rain, hail, frost, wind, sand, lightning, dust, salt spray...

Associated levels:

- **Low:** No exposure (indoors)
- **Medium:** Indirect exposure (hold, station concourse)
- **High:** Direct exposure (outdoors)

Phase	User risk	Mobility	Handling	Exposure to	Overall risk
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		system	of the product	the elements	
Inactivity	Low	Low	Low	Low	Low
Mobilier statique	Medium	Low	Medium	Low	Medium
Mobilier en mouvement	Medium	High	High	Low	High
Freinage	Medium	High	High	Low	High
Installation patient	Medium	High	High	Low	High
Nettoyage	Medium	Low	Low	Low	Low

Assessment of the overall risk of exogenous failure: **MEDIUM**

This product category is subject to a high risk of exogenous failure. The main exogenous failure risks for the product are as follows:

- Failure to follow cleaning product instructions
- Exposure to liquids and other potentially damaging substances:
 - Ink
 - Eosin and medical products
 - Food/sauces/confectionery
 - Clothing and dyes
 - Blood, urine and other bodily fluids
 - Beverages: coffee, wine, soft drinks, alcoholic drinks
- Tip-over
- Impacts against walls
- Excessive forces applied to pedals and adjustment mechanisms

Given the relatively high risk of exogenous failure, particular attention shall be paid to the provision of operating and maintenance manuals, as specified in Chapter 6, Documentation.

VII. ELIGIBILITY

Candidate commitment

The candidate's eligibility in a quality certification process must be consistent with their existing values and strategies.

The company has not been accused or found responsible (information/material evidence, subpoena), of ethical violation, of commercial practices clearly contrary to quality and ethics (practice of planned obsolescence, industrial espionage, fraud -tax) or major environmental impact over the last 10 years where considerable and appropriate efforts have been put in place to: repair the damage caused, prevent it from happening again, reduce their impacts.

The manufacturer has all the necessary rights over the products and is the sole holder of property rights of any kind over the products, including in particular the designs, patents and trademarks relating thereto.

The products are not subject to any dispute of any nature whatsoever from any third party. The products are not likely to harm public order or good morals, to provoke protests from third parties, or to contravene the legal provisions in force.

For the marketing of the products, the manufacturer agrees to its obligations and strictly complies with all legal provisions (directives, regulations, standards, laws) relating to the protection of human health, safety and the protection of the environment prevailing in the geographic areas of product distribution and in relation to its product categories. For the European Economic Area, products must therefore obey European legislation and be in compliance with the "CE" marking for the products concerned.

VIII. LABEL CRITERIA

Environmental performance and/or energy mandate

PR.1. Protection of health, safety and environment

Criterion Prerequisites

Within the framework of respect for human health, the safety of people, installations and protection of the environment, the producer proves that he deploys actions according to a level of requirements compliant at least with the prerogatives of the European directives 2011/65/EU and (EC) No 1907/2006 relating to the limitation of the use of certain dangerous substances in electrical and electronic equipment where necessary.

Method of proof: For products distributed in geographical areas potentially covered by regulatory prerogatives establishing requirements similar to the European market in terms of limiting the use of certain dangerous substances in the EEA, proof of compliance with these regulatory requirements will be used. method of proof in compliance with the PSR of this criterion if necessary.

- ❖ For large companies (more than 5,000 employees), the main site(s) involved in the production of the product shall hold certification to an international environmental management standard.
 - Frame
 - Upholstery
 - Electric motor

Method of proof: ISO 14001 certification issued by an accredited third-party certification body.

- ❖ Compliance with restrictions on substances contained in mattresses and upholstery that may be of concern to human health or the environment.

Method of proof: Material characterisation through product specifications and/or certification, such as:

- CertiPUR certification
 - OEKO-TEX compliance certified in accordance with EN ISO 17050-1
- ❖ The main site(s) involved in manufacturing the product shall hold certification against an international standard addressing the safety of medical electrical equipment, where applicable.

Method of proof: Certificates issued by an accredited third-party conformity assessment body:

- *IEC 60601-1: General requirements for basic safety and essential performance of medical electrical equipment, certified by an accredited third-party conformity assessment body.*
- *EN IEC 61000-6-1: Electromagnetic compatibility (EMC) – Part 6-1: Generic standards – Immunity standard for residential, commercial and light-industrial environments.*
- *EN 62133:2012: Safety of portable lithium-ion cells and batteries.*
- *EN 62281:2013: Safety of electronic equipment using cells and batteries.*
- *EN 61960: Standards for rechargeable cells and batteries.*
- *European Directive 93/42/EEC concerning medical devices.*
- *Regulation (EU) 2017/745 on medical devices.*
- *ISO 14971: Application of risk management to medical devices.*
- *ISO 10993: Biological evaluation of medical devices.*

❖ To reduce the environmental impact of the manufacturing phase, where the company does not hold certification against an international environmental management standard, the manufacturer shall implement at least two of the following measures:

- Paints or other coatings used in the manufacture of chairs and stretchers shall be water-based, bio-based or covered by third-party ISO 14001 certification.
- The site responsible for coating and painting operations shall hold third-party certification against an environmental management standard such as ISO 14001.
- Chair and stretcher frames and structures shall contain recycled material at the following minimum levels:
 - 17% for steel
 - 28% for stainless steel
 - 80% for cast iron
 - 80% for aluminium

Method of proof: Paint composition and characterisation. Third-party certification demonstrating the environmental attributes of the paints used, based on recognised test standards. Declaration of origin for the materials used in the body structure.

❖ The manufacturer shall reduce the proportion of non-recoverable plastic packaging waste through the following measures:

- At least 95% by weight of all packaging waste shall be recycled and/or recyclable and/or reusable.
- For non-reusable packaging, non-recyclable packaging components weighing more than 25 grams shall be manually separable into individual components.
- Packaging made from bio-based materials shall hold recognised third-party certification demonstrating sustainable resource management.

Method of proof: Packaging composition and characterisation.

PR.2. Energy and/or environmental performance

Criterion Prerequisites

As part of reducing the impacts linked to energy consumption or pollution emissions, the producer demonstrates the environmental and/or energy performance of its products. It proves that it deploys actions according to a level of requirements consistent, at a minimum, with the prerogatives of the European (EU) directives and/or regulations 2009/125/EC (including its implementing measures) on the ecodesign of energy-related products and (EU) 2017/1369 (including delegated regulations) on energy labeling of products if the product claiming the LONGTIME® label is concerned.

Method of proof: For products distributed in geographical areas potentially covered by regulatory prerogatives establishing requirements in terms of energy efficiency, eco-design and energy display similar to the European market, proof of compliance with these requirements regulatory requirements will serve as a method of proof in compliance with the PSR of this criterion if necessary.

PR.3. End of life management of equipment

Criterion Prerequisites

As part of the management of end-of-life equipment, the producer proves that it deploys actions for the recovery, recovery and effective treatment of used products according to a level of requirements that complies at least with the prerogatives of the European directives 2012/19/EU of July 4, 2012 relating to the prevention and treatment of waste depending on the target product group.

Method of proof: In geographic distribution areas covered by regulatory prerogatives establishing product collection and recycling requirements, proof of compliance with these regulatory requirements will serve as a mode of proof in compliance with the PSRs of this criterion if necessary.

- ❖ Upon written request, the manufacturer shall take back products at the end of their service life.
 - Products that are still functional shall be donated to a charitable organisation to meet its medical equipment needs.
 - Products that are no longer functional shall be sent to a treatment facility for dismantling.

Method of proof: Ecodesign measures assessed during the audit by the appointed conformity assessment body.

Conception

I.1.1. State of the art and technical solutions

Criterion KO

The manufacturer identifies and records in a technical sheet the constraints on the use of the product and its different parts. It justifies reliable and qualitative design choices and technical solutions with regard to these constraints.

Method of proof: The methodologies used may be based on standards such as:

- EN 45552: General method for the assessment of the durability of energy-related products
- EN 60721: Classification of environmental conditions
- IEC 60605: Equipment reliability testing
- IEC 61123: Reliability testing – Compliance test plans for success ratio
- EN 61124: Reliability testing – Compliance tests for constant failure rate and constant failure intensity
- EN 61649: Weibull analysis
- EN 62506: Methods for product accelerated testing

General methods of proof for this criterion:

- CE marking database
- Supplier quality data (technical specifications, ISO 9001:2015 certification, other certifications, etc.)
- Any documentation or software-based evidence supporting compliance, such as:
 - Internal product technical data sheet
 - Functional analysis tool
 - Design study (operation, materials and stresses arising from use)
- In-warranty and out-of-warranty failure rates: the product shall demonstrate failure rates below the sector market average.
- Accelerated life testing. Given the limited test duration, scientifically sound and robust extrapolation calculations using an acceleration factor shall enable the results to be extrapolated to the product's full maximum service life, demonstrating resistance to stresses above the sector market average.

Tests specific to the product family and/or its components, based on mandatory standards associated with safety directives and voluntary standards, assessing resistance to stresses arising from use and, for voluntary tests, demonstrating resistance above the sector market average:

- EN 60601-1: General requirements for basic safety and essential performance of medical electrical equipment, certified by an accredited third-party conformity assessment body.
- EN 60068-2-38:2009: Resistance of components to temperature and humidity.
- EN 1865-1+A1: Patient handling equipment used in road ambulances – Part 1: General stretcher systems and patient handling equipment.
- EN 1865-5: Patient handling equipment used in road ambulances – Part 5: Stretcher support.
- EN 1865-2+A1: Patient handling equipment used in road ambulances – Part 2: Power assisted stretcher.

❖ Resistance to mechanical stresses

- Mechanical loads applied to frames: compression, tension, bending, shear, torsion, vibration, friction and impact
- Mechanical loads applied to actuators and mechanisms used to move the various product sections (lifting, etc.)
- Mechanical loads applied to mattresses and upholstery: friction, abrasion, bending and tearing
- Mechanical loads applied to the remote control and its cable: drops, impacts, bending and tension
- Mechanical loads applied to the mains power supply cable

Specific methods of proof:

Actuators

- *Strength and operation of hydraulic cylinders: standards such as ISO 10100/ISO 6020*
- *Strength and operation of pneumatic cylinders: standards such as ISO 7285/ISO 6431*

Frames

- *Tensile, compression, bending, fatigue and mechanical testing of frames and structures*
- *Impact resistance testing: standards such as DIN EN ISO 148-1 (Charpy)*

Remote control and cable

- *Degrees of protection provided by enclosures for electrical equipment against external mechanical impacts (IK code) EN 62262*
- *Cable bending tests*

Wheels

- *Compliance with EN 12531*

Mattresses

- *ISO 2439, Method B: Determination of indentation hardness*
- *ASTM D3574, Test H: Standard test methods for flexible cellular materials*
- *ISO 1856, Method A: Compression set*
- *ISO 1798: Determination of tensile strength and elongation at break*
- *Mattress foam density shall be at least 30 kg/m³.*

Upholstery

- *ISO 1421: Determination of tensile strength and elongation at break*
- *ISO 5402: Determination of the flex resistance of leather*
- *ISO 13935-1 and/or ISO 13936-2: Determination of maximum force to seam rupture*
- *ISO 4674-01: Determination of tear resistance*
- *EN ISO 3758: Textiles – Care labelling code using symbols*
- *ISO 5077: Determination of dimensional change in washing and drying*
- *EN ISO 20932: Textiles – Determination of the elasticity of fabrics*
- *ISO 5981: Determination of resistance to combined shear flexing and rubbing*
- *ISO 5470-2: Martindale abrasion resistance*
- *ISO 105-B02/B04/X12: Colour fastness to light and weathering, and to wet and dry rubbing*

❖ **Resistance to thermal stresses**

- High temperatures: motor overheating, hot liquids

Specific methods of proof:

- *Thermal management with overheating protection through technical solutions (ventilation and cooling) and/or product design features (ventilation openings, spacing, thermal decoupling, heat sinks, etc.)*
- *Temperature sensors and a controlled shutdown function*
- *Temperature-sensitive circuit breakers*

❖ Resistance to ingress, liquids and corrosion

- Corrosion caused by cleaning chemicals: resistance of all components exposed to aggressive cleaning agents, including frames, mattresses and upholstery
- Liquid ingress: bodily fluids, beverages, food and cleaning agents
 - Liquid detection that triggers shutdown of the electronics
 - Use of circuit breakers to protect against short circuits
- Resistance to the ingress of particles and foreign matter: dust, hair and other small objects liable to cause failures if they enter mechanical or electrical components

Specific methods of proof:

- *Compliance with an IP rating appropriate to the conditions of use, as defined in EN 60529*
- *EN 15973: Resistance to soiling and to urine and blood stains*
- *EN ISO 846, Method A: Resistance to fungal growth*
- *ISO 1420: Determination of resistance to water penetration*
- *Protection of the operator control terminal against liquid and solid ingress, with a minimum rating of IP6*

❖ Resistance to electrical stresses

- Electrical discharges, electrical overloads and component degradation: protective devices
- Component degradation: components dimensioned to achieve the expected product service life
- Battery performance retention over time: lithium-ion batteries shall retain at least 50% of their charge capacity after 300 cycles.

Specific methods of proof:

- *Electrostatic discharge immunity testing, such as IEC 61000-4-2*
- *Electrical overstress (EOS) robustness testing, such as IEC 61000-4-5*
- *Battery cycling tests*

❖ Resistance to UV radiation

- Resistance to ultraviolet radiation: a level of protection ensuring the robustness of UV-sensitive components

Specific methods of proof:

- Colour fastness testing, such as ISO 105-B02
- UV resistance testing of non-metallic materials, such as ASTM G155

I.1.2. Production

Major criterion

The manufacturer has processes enabling it to control and maintain constant quality of manufacturing and assembly in production.

- ❖ The main site(s) involved in the production of the product shall hold certification to an international quality management standard.

Method of proof:

- *ISO 13485 certification issued by an accredited third-party conformity assessment body.*
- *EN 60601-1 certification issued by an accredited third-party conformity assessment body.*

I.1.3. Consumable parts and accessories

Major criterion

Consumable parts, accessories and parts requiring regular maintenance comply with accessibility scale A.

- ❖ Accessibility scale limited to 3 steps and 5 minutes

Consumable parts : parts intended to be replaced, subject to wear during use of the device.

- **Upholstery assembly**
 - Mattress
- **Wheel assembly and mobility system**
 - Wheel tread

Accessory parts: parts that support operation without forming part of the product itself.

- Arm support
- Cushion
- Trays (general-purpose/meal/bottle holder/patient tray)
- Stirrups
- Paper roll dispenser
- X-ray cassette holder
- Transport straps
- Side rail covers
- Headboard and footboard
- Rods
- Reading light
- Weighing scale
- Surgical rail
- Safety belts

Maintenance parts

- **Upholstery assembly**
 - Upholstery/seat

Method of proof: Visual inspection and real-time demonstration to the inspection body mandated during the on-site audit.

I.1.4. Security elements

Criterion KO

The replacement and/or rearming of product and/or user safety elements is provided by the manufacturer. These elements respect accessibility scale B.

These are all the active and passive parts necessary to protect against risks associated with the use of the product.

❖ Accessibility scale limited to 10 steps and 15 minutes

▸ **Electrical and electronic assembly**

- Thermal fuses (electric motor, drive mechanism, etc.)
- Position or safety sensor or switch (e.g. Hall-effect sensor, microswitch)
- Electronic locking system (switch, position switch)
- Torque limiter

Method of proof: Visual inspection and real-time demonstration to the inspection body mandated during the on-site audit.

I.1.5. Vulnerable parts

Criterion KO

Vulnerable parts include parts exposed to a high rate of accidental user breakage. The replacement of these parts complies with accessibility scale B.

❖ Accessibility scale limited to 5 steps and 15 minutes

▸ **Medical furniture body assembly**

- Bumper system

▸ **Control assembly (start-up, settings, programmes, etc.)**

- Remote control
- Remote control cable

Method of proof: Visual inspection and real-time demonstration to the inspection body mandated during the on-site audit.

I.1.6. Non usage

Minor criterion

The manufacturer identifies the consequences of non-use of the product and must inform the consumer in the recommendations for use of the minimum use necessary for the proper functioning of the product.

- ❖ Applicable: Risk of deep battery discharge
Period of non-use after which this risk is considered relevant: 1 year.

I.1.7. Unproven technology

Criterion KO

The manufacturer provides information on the unproven technology in its product. It must provide the means implemented to guarantee its reliability or ensure that the normal use of the product does not depend on this technology.

Method of proof: Real-time demonstration to the inspection body mandated during the on-site audit.

I.1.8. External source parts

Minor criterion

The manufacturer records external source parts purchased and/or subprocessed. It must provide information relating to their origin and quality.

- ❖ Particular attention will be paid to the following elements:
 - Actuator-related parts (mandatory batch or product quality assurance through certification by a third-party notified body)
 - Upholstery (mandatory batch quality assurance through quality certification)

Method of proof: Supplier declaration and demonstration of quality management practices to the appointed conformity assessment body during the on-site audit.

I.1.9. Reliability plan

Minor criterion

The manufacturer provides its own FMEA, FMEA or internal audit and identifies the changes implemented to improve the reliability and/or repairability of the product. Corrections or improvements already made to the product are indicated.

I.1.10. sub-assembly

Major criterion

The product design must only use subassemblies on technical justification or proof of reliability. Without technical justification, the subassemblies must be subject to a standard reconditioning and/or exchange route where the manufacturer demonstrates the economic interest for the user.

Scalability

I.2.1. Software

Major criterion

The manufacturer ensures that the original performance of its product is maintained during OS updates, without a time limit. The manufacturer identifies and records the means it uses to monitor the maintenance of these post-upgrade performances.

- ❖ Software version management is facilitated on the product, with software version compatibility ensured even for the oldest products still in use.

Method of proof: Embedded software developed in accordance with IEC 62304. Demonstration during the audit of the procedures for updating, correcting and flashing the software on models of ages representative of products in use on the market.

Traceability

I.3.1. Study and failure rate

Minor criterion

The manufacturer provides breakdown rates and/or indicators enabling the reliability of the product to be monitored at least until the last unit of the model concerned is placed on the market.

- ❖ Particular attention will be paid to the following failures:
 - Short circuit (electronic board, component, printed circuit board)
 - Mattress/upholstery failure: tears, wear, etc.
 - Wheel failure
 - Frame failure: impact damage, cracks, failed welds, corrosion
 - Control module failure: remote control, remote control cable
 - Lifting mechanism failure: pedals, actuators
 - Electric motor failure
 - Poor-quality or defective armature insulation
 - Unsuitable motor power rating
 - Electronic failure
 - Short circuit (electronic board, component, printed circuit)
 - Power supply board failure
 - Display module malfunction (backlighting, LEDs, etc.)
 - Control system failure (buttons, touch interface, electronic board, programmer)

I.3.2. Identification number

Minor criterion

The manufacturer uses an identification number or method on each product.

Method of proof: In geographic distribution areas covered by regulatory pre-rotations establishing identification requirements, proof of compliance with these regulatory requirements will serve as a mode of proof in compliance with the PSRs of this criterion if necessary.

Disassembly

II.1.1. Product packaging

Criterion KO

Brings together all the product's covering parts (cover type) to protect the internal components from the outside.

The body of the product is removable and allows access to internal elements while respecting accessibility scale B. Permanent assemblies are prohibited unless the nature or use of the product justifies it.

- ❖ Accessibility scale limited to 5 steps and 10 minutes
 - **Medical furniture body assembly**
 - Covers, lids and cladding panels (front/rear, side, top/bottom)
- ❖ Unjustified permanent assemblies are not permitted.
- ❖ For clip-fastened assemblies, verification of clip quality and the availability of information on clip locations.

Method of proof: Visual inspection and real-time demonstration to the inspection body mandated during the on-site audit.

II.1.2. Access to functional parts

Major criterion

Parts related to the operation or use of the product.

Access to functional parts cannot exceed accessibility scale C.

- ❖ Accessibility scale limited to 15 steps and 20 minutes
 - **Medical furniture body assembly**
 - Mobile section frame
 - Control panel
 - Mattress platform frame
 - Push handle

- Various holders (for bottles, IV poles, etc.)
- Headrest
- Wrist rest
- Footrest
- Side rails
- **Electrical and electronic assembly**
 - LEDs/displays/visual mode indicators
 - Interference suppression coil
 - Relays
- **Mechanical joint sealing and stabilisation assembly**
 - Sealing components (O-rings, rings, lip seals, silicone, etc.)
 - Fastening components (screws, bolts, circlips, washers, etc.)
 - Stabilising components (springs, spacers, trays, bearings, etc.)
 - Linear motion mechanism (slide rails)

Method of proof: Visual inspection and real-time demonstration to the inspection body mandated during the on-site audit.

II.1.3. Access to priority parts

Major criterion

Functional parts but characterized by proven criticality in the event of a malfunction or breakdown (sometimes called critical parts).

Access to priority rooms complies with accessibility scale B or has been the subject of a reliability plan.

❖ Accessibility scale limited to 10 steps and 15 minutes

- **Electrical and electronic assembly**
 - Power circuit boards
 - Control circuit boards
 - Electronic control module
 - Electronic display module
 - Analogue or digital display
 - Electric motor capacitor (start, run)
 - Batteries
 - Power supply cable
 - Ribbon cables
 - Connectors and sockets
- **Electric motor assembly**
 - Rotor
 - Stator
 - End shield
 - Gearbox

- Bearing
 - Ball screw: tube, sleeve, washers
 - Motor nut
 - Motor shaft
 - **Wheel assembly and mobility system**
 - Swivel castors
 - Lockable castors
 - Brake and steering pedals
 - Steering system with a central castor and integrated electric motor
 - **Control assembly (start-up, settings, programmes, etc.)**
 - Control buttons/handles (touch-operated, mechanical)
 - Remote control
 - Control pedals for the various lifting/tilting mechanisms
 - **Height adjustment, tilt and mechanical actuation assembly**
 - Shaft or torque transmission system (direct or indirect)
 - Bearings
 - Raising/lowering mechanisms
 - Pneumatic actuator
 - Hydraulic actuator
- ❖ The fixings of the different priority parts of the product having both a function must be removable and reusable (Class A standard EN 45554)
- In the event that the fixing system cannot be reused, it must be supplied with the replacement part to allow resolution of the failure or maintenance scenario.

Method of proof: Visual inspection and real-time demonstration to the inspection body mandated during the on-site audit.

II.1.4. Sub-assembly connectors (internal parts)

Major criterion

The connectors of the replacement subassemblies must not interfere with the repair of the product.

- ❖ All connector fixing elements must be at least removable (class B standard EN 45554).

Method of proof: Visual inspection and real-time demonstration to the inspection body mandated during the on-site audit.

II.1.5. Batteries

Criterion KO

The manufacturer provides a solution for replacing the batteries of autonomously operating devices.

❖ Applicable

II.1.6. Disassembly tools

Major criterion

Disassembly of the product does not require a proprietary tool, apart from regulatory justification.

- ❖ No regulatory justification identified
- ❖ [List of tools in accordance with the list in table A2 of standard EN 45554](#) and supplemented with basic tools specific to the target product group
 - Extractor of bearings and/or bearings that may exist in electric motors or transmission systems
 - Joint extractor
- ❖ Tolerance allowed for proprietary tools provided on request at no cost additional with the spare part.

Method of proof: Visual inspection and real-time demonstration to the inspection body mandated during the on-site audit.

Documentation

II.2.1. Exploded diagram

Major criterion

The manufacturer makes available to users, directly or indirectly via its partners or its network, diagram(s) or exploded view(s) of the product as well as a nomenclature of the parts and subassemblies of the product.

II.2.2. Exploded diagram

Minor criterion

The manufacturer references and delivers more specific exploded views to help identify and name a part.

II.2.3. Fault code

Major criterion

User and repairer fault codes must be present in the respective documentation and/or accessible on the manufacturer's website.

II.2.4. Repair Manual

Minor criterion

The manufacturer makes the information necessary for repairing the product accessible to repairers OR must justify economically viable alternatives for the end user.

- ❖ All documents necessary for resolving failure scenarios must be exhaustive and accessible (Class A Table A.10 of standard EN 45554) for all professionals in the sector and as a priority:
 - A disassembly diagram or exploded view
 - A technical instruction manual for resolving failure scenarios
 - A list of necessary repair and testing equipment
 - Component and diagnostic information (such as theoretical minimum and maximum values for measurements)
 - Wiring and connection diagrams
 - Error and diagnostic codes (including manufacturer-specific codes, if applicable)
 - Instructions for installing relevant software and firmware, including reset software
 - Information on how to access data relating to failure incidents if they are recorded in the product

Method of proof: Visual inspection and real-time demonstration to the mandated inspection body during the documentary audit or on-site audit.

II.2.5. Troubleshooting software packages

Minor criterion

The fault diagnosis software packages must be free of rights after the full warranty period with regard to the end date of manufacture of the product.

Spare parts

II.3.1. Nomenclature

Major criterion

All spare parts or subassemblies are uniquely named and coded to facilitate identification and ordering of parts.

II.3.2. Availability time

Criterion KO

The manufacturer commits in its General Terms and Conditions or via commercial communication to the availability of spare parts or replacement parts for the product for a minimum of 5 to 10 years from the placing on the market of the last unit of the model concerned. The minimum availability time required is determined in the sectoral appendix.

- ❖ Availability of spare parts 10 years minimum (Class A - Long-term accessibility; Table A9 according to standard EN 45554)

Method of proof: Mode of proof: Demonstration to the mandated inspection body during the documentary audit or on-site audit (general conditions of sale).

II.3.3. Supply time

Minor criterion

For functional parts or sub-assembly, the manufacturer has a minimum reserve to meet the probability of demand for said part OR justification for a procurement process within identical deadlines.

II.3.4. Price of spare parts

Major criterion

The terms and conditions for purchasing spare parts are detailed (average price, distribution network, etc.). The manufacturer makes every effort to limit the total price of functional parts to the maximum recommended selling price excluding tax of the product.

The value of one of these functional parts cannot exceed the set percentage of the maximum recommended selling price excluding tax of the product.

- ❖ Percentage set at 25%. A tolerance is allowed for parts whose PRU would exceed 25%.
- ❖ All replacement parts must be accessible.

Method of proof: Visual inspection and real-time demonstration to the mandated inspection body during the documentary audit or on-site audit.

II.3.5. Price of delivery costs

Minor criterion

The manufacturer delivers the spare parts at actual shipping and preparation costs or offers alternative solutions reducing the cost of receiving the spare parts.

After-sales service under warranty

II.4.1. Contact du SAV

Minor criterion

The maximum time for opening an after-sales service file must not exceed 2 working days.

II.4.2. Support

Major criterion

The manufacturer provides the end user with an after-sales service network in line with its direct distribution network.

II.4.3. Repair policy

Major criterion

Repair must take precedence over replacement.

Out-of-warranty after-sales service

II.5.1. After-sales service network

Minor criterion

The user is provided with the means to facilitate the repair of his product outside of warranty. To support the product to be repaired, the manufacturer must provide the user with the benefit of its distribution and repair network.

Free long-term warranty

III.1.1. Warranty time

Criterion KO

The warranty period with presumption of prior history of the defect is determined in the sectoral annex. This time cannot be less than 24 months.

- ❖ 24 months minimum

Method of proof: Demonstration to the mandated inspection body during the documentary audit or on-site audit (general conditions of sale).

III.1.2. Warranty conditions (beyond the legal conformity period)

Major criterion

For product categories considered to be “highly useful”, the manufacturer provides for the provision of a replacement item to the user during the period of downtime of the product for repair.

- ❖ Product not considered of much use
-

III.1.3. Disclaimer of warranty

Major criterion

The warranty exclusions must not be excessive with regard to the normal conditions of use of the product. They will be defined in the sectoral annex.

- ❖ Warranty exclusions that may be considered unfair:
 - Surface micro-scratches
 - Stains
 - Signs of minor impacts or knocks

Method of proof: Demonstration to the mandated inspection body during the documentary audit or on-site audit (general conditions of sale).

III.1.4. Assignment of Warranty

Major criterion

The manufacturer sets up a transferable guarantee system.

III.1.5. Original package

Minor criterion

Return of the original packaging cannot be required for warranty coverage.

Use and care instructions

III.2.1. Usage information provided

Major criterion

The manufacturer delivers with the product a notice with advice on use and maintenance of the product. This information must be exhaustive and relevant in order to reduce the exogenous failure rate.

- ❖ The manufacturer clearly makes the user aware, via the instructions and/or its website, of responsible use of the device.
 - Maintenance with particular emphasis on the concept and importance of descaling
 - Use
 - Valorization of consumables
 - Repair

Method of proof: Visual inspection and real-time demonstration to the mandated inspection body during the documentary audit or on-site audit (physical and/or digital instructions for use).

III.2.2. Usage information provided

Major criterion

The use and maintenance advice booklet is clear, simple and accessible (adapted font size, vocabulary, language and print quality), so as to be easily understandable by end users.

III.2.3. Access to information

Minor criterion

Information relating to the use and maintenance of the property must be available in digital version on simple request or freely accessible on the manufacturer's website.

IX. THANKS

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ISO – International Organization for Standardization

