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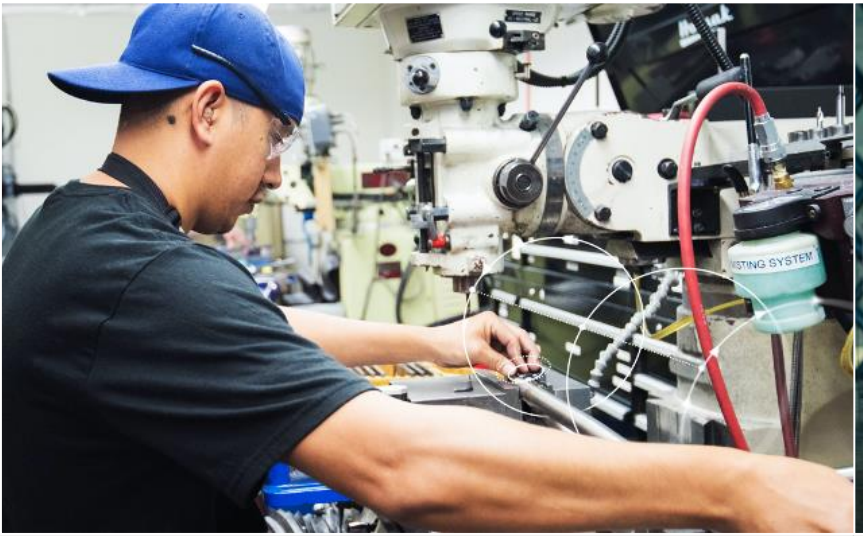
Requirements for Wheelchair Testing Facilities – GLP and ISO 17025



Good Laboratory Practices
GLP

ISO

ICS › 03 › 03.120 › 03.120.20

ISO/IEC 17025:2017

General requirements for the competence of testing and calibration laboratories

permobil

ISO/IEC 17025 enables laboratories to demonstrate that they operate competently and generate valid results, thereby promoting confidence in their work both nationally and around the world.

It also helps facilitate cooperation between laboratories and other bodies by generating wider acceptance of results between countries. Test reports and certificates can be accepted from one country to another without the need for further testing, which, in turn, improves international trade.

Year of publication: 2017 | Edition: 1

A free publication about ISO/IEC 17025, and how it can help testing and calibration laboratories demonstrate their capacity to deliver trusted results.

DOWNLOAD

More on ISO/IEC 17025

https://www.iso.org/ISO-IEC-17025-testing-and-calibration-laboratories.html

US FDA Requirements

Good Laboratory Practice (GLP) required

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=58

European Requirements -2021 Medical Device Directive

Good Laboratory Practice (GLP) required

6. PRODUCT VERIFICATION AND VALIDATION

The documentation shall contain the results and critical analyses of all verifications and validation tests and/or studies undertaken to demonstrate conformity of the device with the requirements of this Regulation and in particular the applicable general safety and performance requirements.

6.1. Pre-clinical and clinical data

(a) results of tests, such as engineering, laboratory, simulated use and animal tests, and evaluation of published literature applicable to the device, taking into account its intended purpose, or to similar devices, regarding the pre-clinical safety of the device and its conformity with the specifications;

(b) detailed information regarding test design, complete test or study protocols, methods of data analysis, in addition to data summaries and test conclusions regarding in particular:

— the biocompatibility of the device including the identification of all materials in direct or indirect contact with the patient or user;

— physical, chemical and microbiological characterisation;

— electrical safety and electromagnetic compatibility;

— software verification and validation (describing the software design and development process and evidence of the validation of the software, as used in the finished device. This information shall typically include the summary results of all verification, validation and testing performed both in-house and in a simulated or actual user environment prior to final release. It shall also address all of the different hardware configurations and, where applicable, operating systems identified in the information supplied by the manufacturer);

— stability, including shelf life; and

— performance and safety.

Where applicable, conformity with the provisions of Directive 2004/10/EC of the European Parliament and of the Council (1) shall be demonstrated.

DIRECTIVE 2004/10/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of 11 February 2004

on the harmonisation of laws, regulations and administrative provisions relating to the application of the principles of good laboratory practice and the verification of their applications for tests on chemical substances (codified version)

1. Member States shall take all measures necessary to ensure that laboratories carrying out tests on chemical products, in accordance with Directive 67/548/EEC, comply with the principles of good laboratory practice (GLP) as laid down in Annex I to this Directive.

CE

36304 44..44 (europa.eu)

European Requirements

Manual and Power Wheelchairs

ISO 17025

EUROPEAN INNOVATION PARTNERSHIP
on Active and Healthy Ageing

European Commission > EIP on AHA > Standards > Healthcare > Personal autonomy > EN 12183:2014

About the partnership | Action Groups | Reference Sites | I2M | Blueprint | MAFE

EN 12183:2014

Subject:
Healthcare

Sub-subject:
Personal autonomy

Reference:
EN 12183:2014

Title:
Manual wheelchairs - Requirements and test methods

Kind of resource:
Standard

Year of publication:
2014

URL:
http://standards.cen.eu/dyn/www/f?p=204%3A110%3A0%3A%3A%3A%3AFSP_PROJECT%2CFSP_O...

Description:
This European Standard specifies requirements and test methods for manual wh intended to carry one person of mass not greater than 250 kg. It also specifies re test methods for manual wheelchairs with electrically powered ancillary equipmer Standard does not apply in total to: - wheelchairs intended for special purposes, s showering or toileting, - manual wheelchairs with handrim-activated power-assist custom-made wheelchairs, - stand-up wheelchairs, and - manual wheelchairs wit kits used for propulsion. NOTE Requirements for electrically powered wheelchair EN 12184.

EUROPEAN INNOVATION PARTNERSHIP
on Active and Healthy Ageing

European Commission > EIP on AHA > Standards > Healthcare > Personal autonomy > EN 12184:2014

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EN 12184:2014

Subject:
Healthcare

Sub-subject:
Personal autonomy

Reference:
EN 12184:2014

Title:
Electrically powered wheelchairs, scooters and their chargers - Requirements and test methods

Kind of resource:
Standard

Year of publication:
2014

URL:
http://standards.cen.eu/dyn/www/f?p=204%3A110%3A0%3A%3A%3A%3AFSP_PROJECT%2CFSP_O...

Description:
This European Standard specifies requirements and test methods for electrically powered wheelchairs, including electrically powered scooters with three or more wheels, with a maximum speed not exceeding 15 km/h intended to carry one person of mass not greater than 300 kg. It also specifies requirements and test methods for battery chargers for wheelchairs and scooters. This European Standard does not apply in total to: - electrically powered wheelchairs intended for special purposes, such as sports, showering or toileting, - manual wheelchairs with handrim-activated power-assisted propulsion, - custom-made electrically powered wheelchairs, - electrically powered stand-up wheelchairs, - manual wheelchairs with add-on power kits used for propulsion and - electrically powered office chairs. NOTE Requirements for manually propelled wheelchairs are specified in EN 12183.

Standards Requirements

“ISO 17025 or Equivalent” Note

ICS › 11 › 11.100 › 11.100.20

ISO 10993-1:2018

Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process

★ The test methods used in the biological evaluation tests shall be sensitive, precise and accurate. When biological testing is conducted, it shall be carried out in accordance with good laboratory practices.

NOTE ISO/IEC 17025 or equivalent.

The test methods should be reproducible (intralaboratory) as well as repeatable (interlaboratory) and robust.

Standards Requirements

Provide guidance here? ISO 17025 / GLP / Equivalent?

ISO/NWI -xx:2020 (E)

ISO TC 173/SC 01

Secretariat: SABS

Wheelchair and Wheelchair Seating Standards Reference – Guide to Applicable Standardized Requirements and test methods

Introduction

Wheelchairs and wheelchair seating are required to meet a wide assortment of performance tests, the specifics of which can vary greatly by the region and market in which the equipment is sold and prescribed. In the absence of a guidance document of potentially applicable standards, many regulators and policy makers have relied on outdated historic tests, or standards that were developed for non-medical, consumer devices. These tests are often inappropriate, as they were not developed in consideration of the specific medical benefits, and potential risks, associated with the use of wheelchairs and wheelchair seating. In fact, the overall clinical benefits of a device or system may sometimes be sacrificed in the design process in order to meet an inappropriate test outcome. The result of uninformed polices can be inhibited innovation, increased cost, and decreased benefit to the end user.

This document is intended to guide regulators, policy makers, prescribers, and product designers to wheelchair-specific standards, as well as additional standards developed outside of ISO TC 173 / SC1, which have been adopted determined by the committee to be appropriate to wheelchairs.

Given the wide range of product applications and individual user needs, as well as environments of use, it is critical that the determination of the suitability of specific standardized tests be based upon a rigorous risk management process, in accordance with ISO 14971. The process should give due consideration to not only product risks, but also the intended benefits of the medical device in supporting the user's goals of health, independence, and quality of life. For these reasons, this list is not intended to be exhaustive or prescriptive, but rather to focus attention upon the potential applicability of standards that have been developed specifically for wheelchairs and wheelchair seating, by experts in clinical practice, academia, industry, and public policy.

We encourage regulatory and policy makers to consider these recommendations, as well as the outcomes of the risk management process of the manufacturer, in determining whether products have been adequately tested to ensure safety and efficacy in their market, for the affected population. We also encourage and welcome direct discussions between the regulators and ISO committees.

Scope

Wheelchairs can be considered to comprise the following components:

a) structural components such as the frame, wheels, etc. which are essential to the mechanical integrity of the wheelchair;

b) power-related components such as motors, energy sources, controllers etc., which are required for the functioning of powered devices on wheelchairs.

c) Integrated or non-integrated devices to manage tissue integrity, such as seat and back support cushions which are intended to have primarily a clinical function to minimize the risks of skin damage (these can also be intended to control or accommodate posture);

d) postural support devices, including, but not limited to, sling seats, sling back supports, arm supports, foot supports, anterior pelvic supports (hip belts), anterior trunk supports (harnesses and chest belts), lateral pelvic/trunk supports (lateral pads) etc., which are attached to the wheelchair and are primarily intended to give postural support to the wheelchair occupant (these can also be intended to aid in pressure redistribution);

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Questions? Please email Kara.Kopplin@Permobil.com