Wheelchair and Wheelchair Seating standards – Reference guide to applicable standardized requirements and test methods

1. Introduction

Wheelchairs and their accessories are medical devices designed to provide mobility to those with mobility impairment. To achieve this, they need to meet performance criteria, for practical and safety purposes. Safety itself comes under the headings, as relevant, of the likes of stability, electrical components, positioning and repositioning parts of the occupant’s body, transportation, cushion and other postural support device performance for appropriate positioning and caring for skin tissue integrity and functional activities of daily living.

The development of international standards for wheelchairs has been allocated to ISO’s Technical Committee TC173 Assistive Products Subcommittee, SC01 Wheelchairs, within which there are a number of Working Groups (WGs), each of which dedicated to a specified aspect around wheelchair design and performance. Currently, the active Working Groups are: WG1 Test Methods, WG6 Wheelchair Restraint Systems, WG10 Requirements and Test Methods for Electro-technical Systems for Wheelchairs, and WG11 Wheelchair Seating.

ISO/TC 173 collaborates with CEN/TC293 Technical Aids for Disabled Persons, WG9 Wheelchairs, which is responsible for EN 12183 and EN 12184 covering manual and electrical wheelchairs respectively. National standards bodies can adopt the International or European standards, as published, or create their own slightly modified versions, adding their own national Foreword. National standards bodies also create their own standards where they feel there is a need for their own jurisdiction, and international coverage is not available.

Standards evolve over time. Once a new standard or revision of a standard has been approved by the responsible Technical Committee, as a new project, the subsequent processes involve the creation drafts as Preliminary Work Items (PWI), Working Drafts (WD), and/or Committee Drafts (CD), which are reviewed by the countries signed up to the relevant Technical Committee. As the technical aspects are firmed up, the drafts enter the public domain as Draft International Standards (DIS) or Final Draft International Standards (FDIS), after which they are published and can then be obtained from your local standards organisation. The current status of the ISO standards can be found at www.iso.org/obp/ui where also the Foreword, Introduction, and Scope of a standard, and the terms and definitions used in that standard can be accessed without charge. Each standard undergoes a Systematic Review every few years to assess whether it should continue in its current form, or be revised and updated, or withdrawn.

Given the wide range of product applications and individual user needs, as well as environments of use for wheelchairs, it is critical that the determination of the suitability of specific standardized tests be also based upon a rigorous risk management process by the manufacturer, in accordance with ISO 14971. This process is based upon the intended use declared by the manufacturer, and should give due consideration not only to product risks, but also to the intended benefits of the medical device in supporting the user’s goals of health, independence, and quality of life.

Many regulators and policy makers (in the absence of a guidance document of potentially applicable standards) have relied on outdated historic tests, or on standards that were developed for non-medical, consumer devices (such as furniture). 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 could well 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, therefore, is intended to guide regulators, policy makers, prescribers, and product designers through the wheelchair-specific standards, as well as additional standards developed outside ISO TC 173 SC1, which are appropriate to wheelchairs. This guide is not intended to be exhaustive, nor prescriptive, but rather to focus attention upon the potential applicability of the 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. It is important to note that many of these tests are not pass/fail, but rather offer objective measures of performance characteristics, to allow for options to be compared and contrasted. We encourage and welcome direct discussions between the regulators and ISO committees.

1.1 Coverage

This document consists of a summary of the documents from the ISO TC 173/SC01 standards working groups’ work programmes. They are specific to wheelchairs, wheelchair transportation, and wheelchair related seating. Relevant (i.e. referenced) biocompatibility standards have been included at the end of the document.

NOTE 1 Wheelchairs, unless stated otherwise, include manual wheelchairs, electric wheelchairs, and three- or four-wheeled scooters, with a maximum speed of 15 km/h designed for a single occupant.

NOTE 2 In this context 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).
### 2. Summary of subject areas covered by each document

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- Flammability
- Biocompatibility
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**Notes:**
- Under revision
- Under preparation
- In preparation
- Published
- Revised
- Edition 2021
3. **ISO Wheelchair and Wheelchair Seating and Related Standards: Summary of scope and coverage**

### 3.1 Quality and Risk Management

In most jurisdictions, wheelchairs and various of their accessories are classified as medical devices. Manufacturers of medical devices are generally expected to have in place appropriate quality management systems. In addition, appropriate risk assessment and management approaches need to be employed. There are relevant standards covering the respective requirements and applications.

**ISO 13485:2016 Medical devices – Quality management systems – Requirements for regulatory purposes**

This document specifies requirements for a quality management system where an organization needs to demonstrate its ability to provide medical devices and related services that consistently meet customer and applicable regulatory requirements. Such organizations can be involved in one or more stages of the life-cycle, including design and development, production, storage and distribution, installation, or servicing of a medical device and design and development or provision of associated activities (e.g. technical support). This document can also be used by suppliers or external parties that provide product, including quality management system-related services to such organizations.

Requirements of this document are applicable to organizations regardless of their size and regardless of their type except where explicitly stated. Wherever requirements are specified as applying to medical devices, the requirements apply equally to associated services as supplied by the organization.

If applicable regulatory requirements permit exclusions of design and development controls, this can be used as a justification for their exclusion from the quality management system. These regulatory requirements can provide alternative approaches that are to be addressed in the quality management system. It is the responsibility of the organization to ensure that claims of conformity to this document reflect any exclusion of design and development controls.

**ISO 14971:2019 Medical devices – Application of risk management to medical devices**

This document covers the process for risk management of medical devices, including software as a medical device. The process described in this document intends to assist manufacturers of medical devices to identify the hazards associated with the medical device, to estimate and evaluate the associated risks, to control these risks, and to monitor the effectiveness of the controls.

The requirements of this document are applicable to all phases of the life cycle of a medical device. The process described in this document applies to risks associated with a medical device, such as risks related to biocompatibility, data and systems security, electricity, moving parts, radiation, and usability.

This document does not apply to:

— decisions on the use of a medical device in the context of any particular clinical procedure; or
— business risk management.

This document requires manufacturers to establish objective criteria for risk acceptability but does not specify acceptable risk levels.
3.2 ISO 7176 series wheelchair standards

In this Clause, wheelchairs, unless stated otherwise, include manual wheelchairs, electric wheelchairs, and scooters, with a maximum speed of 15 km/h designed for a single occupant. There are two Technical Reports numbered in the ISO 13570 series which were compiled to help use various of the ISO 7176 documents available at the time, and these documents are listed first in this Clause.


The purpose of this document is to explain how you can make use of the very technical ISO 7176 documents to select a wheelchair. Please note, however, that this document was last revised in 2005, and that many of the documents of the ISO 7176 series have been revised or added to since then.

This document covers:

- background information on standardized testing of wheelchairs. Discusses how chairs are tested and how information is disclosed.
- general considerations related to choosing a powered or manual wheelchair.
- the occupant’s physical characteristics to the fit of a chair, either manual or powered.
- manual wheelchair test procedures.
- powered wheelchair test procedures with focus on three- and four-wheeled scooters as well as full-sized powered wheelchairs.

In the manual and powered wheelchair sections, the test procedures are grouped into three categories:

- performance,
- safety, and
- dimensions.

For each test procedure, this document includes

- reasons why you might need this information,
- a brief description of the standardized test procedure,
- how the results of the test will be disclosed in the manufacturer’s technical product literature, and
- how to interpret the results of the test for your own situation.


This document, to be used alongside ISO 7176-5, lists the typical values and recommended limits of the important wheelchair dimensions (ready for occupation and folded or dismantled), space for pivoting or reversing between limiting walls and some dimensions worthwhile to estimate usability of the wheelchair as well as determination of the mass of the wheelchair.

This document includes some operating areas when performing special tasks encountered in every day life.

This document provides a method for the measurement of the tipping angles (either wheelchair tipping angle or anti-tip device tipping angle), but this method is not applicable to wheelchairs with lateral anti-tip devices and does not consider sliding on the ground.


This document specifies test methods for determining the dynamic stability of electrically powered wheelchairs, including scooters. This document is not applicable to manual wheelchairs with add-on power kits used for, or to assist, propulsion.


This covers the measurement of the effectiveness of brakes mounted on a wheelchair.

ISO 7176-4: 2008 Wheelchairs – Part 4: Energy consumption of electric wheelchairs and scooters for determination of theoretical distance range

This document covers the theoretical distance range of electrically powered wheelchairs, including scooters.

ISO 7176-5: 2008 Wheelchairs – Part 5: Determination of dimensions, mass and manoeuvring space

This covers the outside dimensions of a wheelchair when occupied by a reference occupant, and the required manoeuvring space needed for manoeuvres commonly carried out in daily life.

This document contains five informative annexes.

Annex A, which specifies methods for the determination of technical dimensions that can be important to the performance of the wheelchair.

Annex B, which provides detailed information about pivot width and reversing width.

Annex C, which provides detailed information about the turning diameter.

Annex D, which provides details on determining the wheelchair longitudinal axis and wheelchair centre-point.

Annex E, which provides guidelines to facilitate improved understanding, design and construction of wheelchairs.

ISO/TR 13570-2 has been compiled as a user’s guide to working with and interpreting this document.

ISO 7176-6: 2018 Wheelchairs – Part 6: Determination of maximum speed, acceleration and deceleration of electric wheelchairs

This document covers the determination of the acceleration and maximum speed of electrically powered wheelchairs, including scooters, on a level surface.


This document specifies a method for measuring the seating and wheel dimensions of a wheelchair with a seat wider than 212 mm.

For wheelchairs not specified within the scope, this document may still give an indication of where measurements should be made.
ISO 7176-8: 2014 Wheelchairs – Part 8: Requirements and test methods for static, impact and fatigue strengths

This document specifies requirements for static, impact, and fatigue strength of wheelchairs, and applies to occupant- and attendant-propelled manual wheelchairs and electrically powered wheelchairs.

ISO 7176-9: 2009 Wheelchairs – Part 9: Climatic tests for electric wheelchairs

This document covers the effects of rain, dust, condensation and the effects of changes of temperature on the basic functioning of electrically powered wheelchairs, but does not include requirements for resistance to corrosion.

ISO 7176-10: 2008 Wheelchairs – Part 10: Determination of obstacle-climbing ability of electric wheelchairs

This document covers the ability of electrically powered wheelchairs, including scooters, to climb and descend obstacles.


This document covers test dummies of any mass greater than or equal to 25 kg, up to 300 kg, in 25 kg increments, to be used in the evaluation of wheelchairs. The aim is to inform the construction of test dummies that will produce comparable results for stability, performance and durability testing of wheelchairs.


This document covers the determination of the coefficient of friction of a test surface that has a rough texture, such as unfinished concrete. In the event that the test method is used for smooth or polished surfaces, care should be exercised that the coefficient of friction is measured as being constant over the whole area of the test surface.


This document covers the power and control systems of electrically powered wheelchairs and scooters. It sets safety and performance requirements that apply during normal use and some conditions of abuse and failure. It also specifies methods of measurement of the forces necessary to operate controls and sets limits on the forces needed for some operations.

ISO 7176-15: 1996 Wheelchairs – Part 15: Requirements for information disclosure, documentation and labelling

This part of ISO 7176 specifies the information, documentation and labelling to be supplied with a wheelchair or provided in the presale specification sheets by the manufacturer.

ISO 7176-16: 2012 Wheelchairs - Part 16: Resistance to ignition of postural support devices

This document has been withdrawn and replaced by ISO 16840-10:2021.

ISO 7176-21: 2009 Wheelchairs – Part 21: Requirements and test methods for electromagnetic compatibility of electrically powered wheelchairs and motorized scooters, and battery chargers

This document covers electromagnetic emissions and electromagnetic immunity of electrically powered wheelchairs and scooters. It is also applicable to manual wheelchairs with an add-on power kit.
This document also covers the electromagnetic compatibility of battery chargers intended for use with electrically powered wheelchairs and scooters.


This document specifies a set-up procedure to be used as a part of the preparation of adjustable wheelchairs for testing. This procedure takes the manufacturer’s instructions into account.


This document covers batteries and battery chargers intended for use with electrically powered wheelchairs. It is applicable to lead acid batteries and chargers intended for use with them. Requirements for chargers are applicable to those with a rated input voltage not greater than 250 V a.c. and a nominal output voltage not greater than 36 V.

ISO 7176-26: 2007 Wheelchairs – Part 26: Vocabulary - under revision

This document provides a vocabulary consisting of terms and definitions used around wheelchairs and associated seating systems.


This document covers stair-climbing chairs and stair-climbing wheelchair carriers where the stair-climbing device climbs backwards up the stairs, with the occupant facing downstairs, and climbs forwards down the stairs with the occupant also facing downstairs.

This document is not applicable to stair-climbing devices which are intended to be operated by children as operating occupants or assistants. It covers electrically powered stair-climbing devices, but not manually powered stair-climbing devices.

This document specifies tests to demonstrate the stair-climbing device's ability to perform safely on stairs with a pitch of 35°, or higher if declared by the manufacturer.


This document covers the safety and performance of a manual and/or power wheelchair that incorporates technology to alter the posture of the wheelchair occupant, which are either electrically or manually operated by the occupant or assistant during normal wheelchair use. This can include recline, tilt, elevate and stand-up mechanisms or a combination of these. In order for a wheelchair to be able to recline, tilt, elevate and/or stand-up, the wheelchair requires additional mechanisms and mechanical structures to allow these features to operate. This document specifies the different functional and strength tests required to test these wheelchairs in critical configurations of their adjustable range.

This document does not cover wheelchairs where the only operator adjustable body support system (OABSS) is adjustable limb or head postural support devices alone (e.g. elevating leg supports).

This document does not include wheelchair and postural support device customization during initial or subsequent setup of a wheelchair for an individual occupant. It also does not reflect other factors that can influence wheelchair stability such as occupant movement, cushion thickness, and the addition of ancillary equipment (e.g. respiratory support items).

ISO 7176-31: TBA Wheelchairs – Part 31 Lithium ion battery technology (Under Development)
This document specifies test methods and requirements of lithium batteries, their chargers and battery management systems when used in powered wheelchairs.

Requirements for chargers are applicable to those with a rated input voltage not greater than 250 V a.c. and a nominal output voltage not greater than 120 V d.c.


This document specifies strength requirements and test methods for wheelchair castor assemblies. The test methods include corrosion, abrasion and fatigue conditions. It applies to castor assemblies of or developed for use in occupant- and assistant-propelled manual wheelchairs and electrically powered wheelchairs.

The document also covers wheelchair castor assemblies not necessarily associated or supplied with a wheelchair. Castors including anti-tip castors that do not touch the ground during wheelchair travel are not included.

3.3 ISO 16840 series wheelchair seating and accessories standards

ISO 16840-1: 2006 Vocabulary, reference axis convention and measures for body segments, posture and postural support surfaces - under revision

This document applies to seating intended to provide postural support within a wheelchair. It specifies:

a) a global coordinate system that permits the determination and recording of a person's posture while seated in a wheelchair;

b) the standard terms and definitions for use in describing both the posture and the anthropometrics of a person seated in a wheelchair;

c) the terms and definitions for describing the dimensions, location and orientation of seating support surfaces, which together comprise the body support system.

This document does not specify any methods for use in measuring a person's seated posture, nor does it define terms for dynamic physiological movements (such as flexion or extension).

This document is applicable to seating other than that intended to be used within a wheelchair.

ISO 16840-2: 2018 Determination of physical and mechanical characteristics of devices intended to manage tissue integrity - Seat cushions

This document covers testing of wheelchair seat cushions intended to maintain tissue integrity and prevent tissue trauma. The properties covered are: frictional properties (sliding resistance); frictional properties (horizontal stiffness); impact dampening; ‘recovery’; loaded contour depth and overload deflection (relates to stability); water spillage (liquid penetration through the cover); biocompatibility (see also Clause 5.6); hysteresis. Annex B summarises the values that might be seen, and their clinical relevance.

This document can also be applied to tissue integrity management devices used as other support systems, as well as to cushions used in situations other than a wheelchair.

ISO 16840-3: 2014 Determination of static, impact and repetitive load strengths for postural support devices - under revision
This document covers test methods for the determination of static, impact, and repetitive load strengths for postural support devices (PSD) with associated attachment hardware intended for use with an undefined wheelchair. This document does not apply to the strength of PSDs under crash conditions in a motor vehicle. This document does not apply to PSDs that are designed to fail under certain static, dynamic, or repetitive loads.

For masses greater than 150 kg or less than 25 kg, appropriate extrapolation of test apparatus dimensions, mounting point separation, etc. are permitted.

**ISO 16840-6:2015 Simulated use and determination of the changes in properties — Seat cushions - under revision**

This document covers means of generating aging effects in a seat cushion that reproduce those seen in use. It provides methods of determining changes in the physical and mechanical properties of seat cushions based on their age and use. It provides a set of tests that simulate wear and tear, which can be useful to validate warranty claims and to provide information about product life, and performance limitations associated with product use.

**ISO 16840-7:TBA Cushion Heat and Water Vapour Testing – in preparation**

Coverage to follow

**ISO 16840-8:TBA Guidelines for the clinical application of ISO 16840-1 – in preparation**

This document is a clinical guide to show how make the measures defined in ISO 16840-1. A preliminary version covering most of what will appear in this document is available in the meantime for free download.

**ISO 16840-9:2015 Wheelchair seating — Part 9: Clinical interface pressure mapping guidelines for seating**

This document guides users around the performance of the tasks that are directly involved in the clinical use of interface pressure mapping (IPM) or are synergistic with its use in a comprehensive wheelchair seating evaluation.

This document does not cover other aspects of the clinical assessment process (e.g. taking a medical history), nor the prescription or treatment process which might arise from an assessment. These guidelines are not meant to be a substitute for clinical reasoning and judgement within the context of a complete assessment.

This document refers to the state of the art of IPM experiences in a seating scenario. Most of the principles covered can be extrapolated to whole body (in bed) or to foot assessments, for example.

**ISO 16840-10:2021 Resistance to ignition of postural support devices – Requirements and test method**

This document addresses components that interface with the human body, such as cushions for positioning, or whose described purpose is that of protecting skin tissue against pressure, shear, and maceration related damage, as well as textile, foam, and plastic-based postural support devices.

This document covers the resistance to ignition by smouldering cigarette equivalent, of integrated or non-integrated components of a wheelchair intended to protect tissue integrity and/or provide postural support. The electronic ignition source is also a simulation of other potential sources of environmental ignition hazards.
This document does not apply to resistance to ignition of structural parts of a wheelchair, nor does it cover changes in resistance to ignition as a result of regular washing or use of the postural support devices, nor does it apply to the control of risks created by electrical and electronic components.

This document describes testing an assembly of the composite of materials as used in the component.

ISO 16840-11:2014 The determination of dissipation characteristics of sensible perspiration into seat cushions - under revision

This document covers the dissipation characteristics of simulated perspiration exposure on wheelchair seat cushions.

ISO 16840-12:2021 Apparatus and Method for Cushion Envelopment Testing

This document covers wheelchair seat cushion immersion and envelopment properties using instrumented indenters to characterize the interface pressure of each indenter and the test cushion by measuring the cushioning effects of immersion and envelopment.

This document includes a method that is specific to 220 mm and 255 mm indenters. Dimensions and loads are provided for the 380 mm indenter to allow for extension of the methods for bariatric applications.


This document covers the determination of lateral stability properties of wheelchair seat cushions by measuring the response from the cushion to a shift in the centre of mass of the load on the cushion. It does not provide information related to anterior-posterior stability, nor to stability contributions from cushion edges.

This document is applicable to cushions used in situations other than a wheelchair.

ISO TS 16840-14:TBA Wheelchair seating – Part 14: Terminology and concepts related to managing external forces to maintain tissue integrity (Under development)

This document covers the human body’s response to postural support systems and particularly highlights the impact of the interface between tissue and postural support devices (PSD) on the maintenance of tissue integrity. It provides a general introduction to biomechanical concepts, phenomena, and terminology.

ISO 16840-15:TBA Wheelchair seating – Part 15: Selection, placement, and fixation of flexible postural support devices in seating (Under development)

This document specifies requirements for the selection, placement, and fixation of flexible postural support devices within seating devices and systems, and to chairs, including wheelchairs and bathroom equipment. Seating devices can be involved in one or more situations, including hoists, static seating, wheelchair seating, shower chairs, etc. The devices enable the seated person (the occupant) to be positioned to maximize their functional activities, and in a safe environment. These requirements have a balance of maintenance of posture and of safety.

This document covers flexible positioning supports (padded or otherwise) used for postural positioning and/or safety. It does not cover belts and harnesses used in transportation for restraint, nor postural support devices made from rigid, nor postural support devices designed solely for use in sports-related seating.
3.4 Transportation-related standards


This document covers wheelchairs, which, in addition to their primary function as wheeled mobility devices, are also likely to be used as forward-facing seats in motor vehicles by children and adults with a body mass equal to or greater than 22 kg. The document applies to complete wheelchairs, including a base frame and seating system, as well as to wheelchairs equipped with add-on adaptive components designed to facilitate compliance with one or more of the requirements.

ISO 10542-1:2012 technical systems and aids for disabled or handicapped persons – wheelchair tie down and occupant restraint systems – Part 1 requirements and test methods for all systems - under revision

This document covers wheelchair tie down and occupant-restraint systems (WTORS). It is applicable to all WTORS that use belt-type occupant restraints that are intended for occupied wheelchairs used as forward-facing seats by passengers and drivers of motor vehicles.

This document is applicable to WTORS intended for use with all types of manual and powered wheelchairs, including three- and four-wheeled scooters, used by children and adults with a body mass equal to or greater than 22 kg. It is applicable also to WTORS designed for limited use with a particular make or model of wheelchair.

ISO 10865-1:2015 Wheelchair containment and occupant retention systems for accessible transport vehicles designed for use by both sitting and standing passengers – Part 1: systems for rearward-facing wheelchair-seated passengers

This document is applicable to wheelchair passenger spaces (RF-WPSs) intended for use by rearward-facing wheelchair-seated occupants, with a body mass greater than 22 kg, when travelling in accessible transport vehicles. It is applicable to systems for use in vehicles used mainly on fixed route services when operated under normal and emergency driving conditions, where passengers are allowed to travel both sitting and standing. It assumes that the maximum acceleration imparted to the vehicle in any direction during emergency driving manoeuvres will not exceed 1G.

The primary purpose of this document is to limit those movements of a rearward-facing wheelchair that can result in hazardous contact with the vehicle interior or injury to other passengers.

ISO 10865-2:2015 Wheelchair containment and occupant retention systems for accessible transport vehicles designed for use by both sitting and standing passengers - Part 2: Systems for forward-facing wheelchair-seated passengers

This document applies to wheelchair passenger spaces that are intended for use by passengers with a body mass greater than 22 kg who remain in their wheelchairs when travelling facing forward in accessible transport vehicles designed to transport both standing and sitting passengers on fixed-route service. It assumes that the maximum acceleration imparted to the vehicle during emergency driving manoeuvres will not exceed 1 G in any direction and rarely exceeds 3 G in frontal crashes.

ISO 16840-4:2009 Seating systems for use in motor vehicles
This document covers test methods and requirements for design and performance of seating systems intended to be used as a forward-facing seat in a motor vehicle when fitted to a manual or powered wheelchair. It evaluates the frontal crashworthiness performance of complete seating systems for occupancy by adults or children of mass equal to or greater than 22 kg.

This document applies to complete wheelchair seating systems, including attachment hardware, designed to be used with a wheelchair base tested as part of a wheelchair system that conforms to ISO 7176-19 performance requirements and that has securement points for use with four-point, strap-type tie downs.

3.5 Biocompatibility of seating materials

ISO 10993-1:2015 Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process

This document provides guidance to determine the applicability of parts 5 and 10.

ISO 10993-5:2009 In vitro cytotoxicity

This part of ISO 10993 describes test methods to assess the in vitro cytotoxicity of medical devices.

These methods specify the incubation of cultured cells in contact with a device and/or extracts of a device either directly or through diffusion.

These methods are designed to determine the biological response of mammalian cells in vitro using appropriate biological parameters.

ISO 10993-10:2010 Biological evaluation of medical devices — Part 10: Tests for irritation and skin sensitization

This evaluation covered by this document is not recommended unless the risk assessment process deems otherwise.