



Showerbuddy Global Limited
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New Zealand

Clinical Evaluation Report

According to the European Commission's MEDDEV. 2.7.1 Rev. 3

1. General Information.

Name o evaluated Device: Shower Chair Family: SB1, SB2T, SB3T

2. Description of the device and it's intended application.

Showerbuddy Toilet and/or Shower Chairs are a medical devices mainly intended for physically handicapped people and their assistants to maintain hygienic procedures in toilets, shower cabins or large bathtubs. They have been designed as assistance tools for the people who have mobility problems. The devices are specifically dedicated for individuals who require additional stable support during washing and excretion. They are intended to be used only as a seating option for toileting, showering and bathing. Their purpose is to help to physically handicapped persons during their hygienic activities. These devices were tested and approved for users weighting up to 160kg.

The devices are made from powder coated aluminium tubing, stainless steel and plastic. They are warm to the touch and corrosion resistant. The devices are equipped following features: 4 caster wheels, parking brakes, adjustable seat height; excrement bucket; padded - water resistant backrest and seat pad made of high density plastic with texture that is friendly and warm to touch and easy to clean; detachable armrests and footrests for user comfort and easy transfer, reclining seat, headrst etc.

Depending on user's needs some of Showerbuddy products are delivered with specially designed transfer system to further improve the comfort and safety of usage for both: user and a carer.

3. Intended therapeutic indications and claims.

The Shower Chair is a medical device intended for individuals who, because of their physical disabilities require seating support when showering or bathing. A therapeutic indications list for usage is very simple concerning symptoms and very wide concerning the disease type and name. Shower & Bath Chairs are recommended for all people who suffer limited mobility of the human motion system and due to that fact they have difficulties in achieving their hygienic activities. Thanks to bath & toilet aids they find it much easier to enter and leave the toilets, shower cabins or bathtubs and to wash, dry, undress or dress themselves. Considered human mobility problems may include many kinds of diseases which tend to limit the capabilities of joints, muscles, bones and nerves responsible for activating the human motions etc.

4. Context of the evaluation and choice of clinical data types.

The evaluation of the device is based on long term usage and experience with similar products on global market. Technical aids for disabled persons are very popular and well established devices, produced for many decades. This gave opportunity for manufacturers, users and medical staff to test them well in regular daily routines and appreciate their advantages.

Because of long existence on market items like that were also well developed and improved along the years by producers, to reach present state of technical and functional abilities.

Along with technical development there were official technical standards developed. They describe very well what kind of functions, safety features, and mechanical solutions should be implemented to keep such products as safe and functional for users as possible.

Main European standard for analyzed device is:

- EN 12182 – “Mechanical aids for disabled persons”

It describes all the principles for safe and reliable design and essential requirements for the concerned devices, labeling and user manual. Analyzed products were tested for conformity with above standard and passed the tests.

- EN 12183 – “Wheelchairs”

It describes all the principles for safe and reliable design and essential requirements for wheelchairs. Some parts of this norm have also reasonable usage for toilet and shower chairs, particularly those equipped with wheels. Analyzed products were tested for conformity with points 7.3 & 7.5 of above standard and passed the tests.

Many professional handbooks and magazines dedicated for education of physical therapists, nurses, assistants and families of disabled persons include information about different bathing equipment with mentioning of shower chairs and their advantages. For preparing this analysis, information from below books was used:

- “Encyclopaedic Dictionary of Rehabilitation” - PZWL (State House of Medical Publishing) 1986
- “Neurorehabilitation. Orthopedic Equipment” - PZWL 2009
- “Child with protracted disease. Care and support” ŽAK (Educational Publishing House) 2006

- “Clinical application of prosthesis, orthosis and auxiliary equipment” Via Medica 2008
- “Rehabilitation equipment” Via Medica 2003
- “Disabled person in society” PZWL 1986
- “Rehabilitation nursery” PZWL 1975
- “Rehabilitation and nursing of physically handicapped persons” Czelej 2002
- “Geriatric nursing” Urban & Partner 2004

The article specially dedicated to discussed topic was published in most popular Polish magazine “Integracja” (Integration) dedicated to society of people connected with rehabilitation and care of disabled persons:

- Bathroom for elderly persons. Article in “Integracja” magazine.

5. Summary of the clinical data and appraisal.

When looking at above mentioned publications, there is a clear picture coming of them, that apart of direct medical rehabilitation procedure for physically handicapped people realized by physical therapy, kinesis-therapy, exercises and positioning, there is an another group of therapeutic processes called: social rehabilitation and elimination of architectural obstacles. This part of rehabilitation can't be forgotten, as it is extremely important not only for actual physical health condition and continuation of clinical therapy of a patient but also for his/her self confidence and mental condition.

For all people it is essential to think and feel that most of daily routines, duties or activities can be fulfilled without external help of an assistant or (at worse) almost without it.

There are many kinds and levels of physical disability depending on disease type, age and other health factors, but it is a main task of all kinds orthopedic

equipment to offer to patients as much of self independence and dignity as it is possible concerning their actual condition.

One of main daily activities for every human being are all bathing and toilet tasks that are necessary because of hygienic, secrete and esthetic purposes. People need and want to be clean because of both: social and hygienic requirements. Most of the so called wide range “bathing” activities have to be repeated few times every day. Some of them are realized on daily bases. It has to be also taken in consideration that all toilet and bathing routines are connected with some level of difficulty and risk of incident, as it is necessary to manage damp or wet places, enter and leave bathtubs, shower cabins, get on and off the toilet bowls etc. User needs to be able to reach different parts of his/her body with comfort and elimination of risk of incident.

For above reasons it is very important to create for disabled people comfortable and efficient tools, that will help to achieve all daily hygienic needs with elimination of pain, discomfort or awkwardness.

The type of devices used in baths can differ depending on user’s condition.

Persons having serious diseases or age-related motion system disabilities can’t achieve self independence and confidence during washing in regular bathtubs or shower cabins. For people like that it is usually necessary to renovate, remodel or rebuild whole bathrooms (which often is the only solution for heavily diseased patients). But if such persons and their assistants are equipped with right tools and with small technical improvements they can still use almost regular bathroom equipment. Such solutions decrease the costs of modifications and are easier to handle by other users of home bathroom.

Among different rails, toilet seat raisers, handles etc. there is an important group of toilet/shower chairs/wheelchairs. Those are essential devices which assist handicapped people during excretion and/or washing.

The most difficult tasks to handle during this activity are: entering and leaving the shower cabin or bathtub, seating down and getting up, reaching to different body parts, dressing and undressing, drying a body with a towel. There are many different aids to solve above mentioned difficulties with electrical bath lifts or ceiling lifts on top, but for a large group of users it is the most efficient to add a mobile multifunctional seating aid. Such device eliminates or at least decreases majority of problems and at the same time it has an important advantages of relatively low price and very easy handling, great mobility and maneuverability.

The shower chairs are usually made of metal frame (aluminum, steel or stainless steel) and plastic or PU seating. The correct structure of reinforcements allow product to be strong enough even for heavy users. At the same time elimination of steel parts takes away the risk of corrosion and product is much lighter it self. This can be a major factor for patients who often aren't strong enough to handle heavy metal made aids.

Shower Chairs are devices which main features for safety and comfort should include:

- Strong structure to carry patient's weight.
- Dimensions which allow chair to fit to most standard doorways, corridors, bathrooms, toilets and shower cabins.
- Height adjustable seat to fit seat height to the user's size and toilet/bathtub height
- caster wheels for maneuvering and parking brakes

- Armrests and backrest are be very helpful for patients with heavier disabilities. They aren't always necessary and their presence depends on individual user's condition and needs. For some users they can be very helpful so they can be an optional equipment or standard feature of more advanced devices .

6. Data analysis.

6.1. Performance.

As it was described in chapter 2, analyzed devices are made of user's friendly aluminum and plastic elements which are warm to touch. Metal parts are powder coated with paint. The chairs are light in comparison with their multifunctionality which makes them easy to handle (putting it in and out the bathtub/shower cabin, adjusting etc.). The devices are equipped with all the necessary features of such products, so they provide easy and practical usage which the chairs are intended for.

But the most important and unique feature of the Showerbuddy product family is patented transfer system built of special bridge frame and track system. This allows for assistant to utilize easy and forceless transfer to chair, to shower cabin, to bathtub etc. This function puts Showerbuddy devices high above an average level of clinical usefulness for similar items. The performance and features of estimated products fulfill all basic demands that are clinically important for comfortable, intended usage and are actually much better than standard requirements.

6.2. Safety.

Apart of usage comfort, easiness, ergonomics and device's performance all above mentioned features and functions have an important impact on product's safety.

Round edges are safe as they avoid the risk of bruises or sores created by big pressure of user's body weight.

The surface of plastic material isn't smooth, but intentionally brushed to avoid slipperiness. Seat Height can be easily adjusted to fit to different user's heights. There are armrests, footrests and headrest that provide stable side support during hygienic activities. They decrease risk of user to fall down.

4 wheels, adjusted correctly support all chair's corners on base that is wider and longer than the seat pad. That secures device from shaking, moving from side to side, tipping over or slipping. Products have standard seat safety belts to stabilize user even more.

All assembly solutions and connections are stable and rigid.

The essential fact for estimation of product safety is, that device was tested for conformity with EN 12182 European Standard for "Technical aids for physically handicapped persons". During that procedure the design, construction, materials and strength of seat were checked. It went through loading tests for prescribed max. user's weight. The device passed positively all required tests.

The number of recorded dangerous events related to this kind of equipment must be virtually marginal as during this evaluation no record of such incidents were found when investigated. This confirms conclusion that the estimated device causes practically no unwanted interactions while used by motorically-challenged individuals.

6.3. Product literature and Instruction for Use.

Device standard features are: user's manual which describes the intended use, safety precautions, indications, assembly, usage, handling, cleaning, technical data and warranty terms. Device is labeled with a sticker that includes information about manufacturer, CE marking and max. user's weight.

7. Conclusions.

Above evaluation shown that because of regular partnership with people and institutions dealing with care of the disabled, as well as due to its close operation with multiple standards and producers for rehabilitation devices, manufacturer of above medical devices has acquired profound knowledge and experience in the sector of mobility aids for handicapped persons.

Analyzed products are a device types commonly known and used among physically handicapped people. Shower Chairs similar to those have been made by other companies for years now and they have become a standard support device for the disabled. The product of this kind has long been in regular use worldwide to assist the disabled in everyday care.

The Showerbuddy products have direct impact on user's life comfort and self confidence. Patients appreciate the simplicity and durability of such products. Other alternatives are more expensive and complicated in everyday usage. Not all patients need such complex devices, so shower chairs answer the basic needs, specially for elder people.

Described device went through all CE marking procedures in accordance with MDD 42/93/EEC Directive and it was tested concerning safety, performance and

product information for conformity with main EN12182, main European Standard created for technical aids used by disabled people.

All above collected and analyzed data enables to safely state that the use of Shower Chairs by Showerbuddy have a reasonable clinical purpose and that it is suitable for applications intended by the manufacturer.

The result of above Clinical Evaluation is positive.

This clinical evaluation analysis has been made by the manufacturer's representative:

Date: 2014-09-16

Signed:

Wojciech Włodarczyk

A handwritten signature in black ink, appearing to read 'Wojciech Włodarczyk', written in a cursive style.

Physical Therapist