CLINICAL EVALUATION REPORT

Name of medical device: Powered wheelchair Sango (electric wheelchair)

Medical Model Models: Sango M Slimline

Risk class of medical device: I

Submitter - Manufacturer:

Dietz Power B.V.
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5708 JV
Helmond
The Netherlands
ID (Identification number): NL856228631B01

Evaluator:
Company: Dietz Power BV
Name: Sjoerd Lintermans
Function: R&D Manager

Qualification and practice of the assessor:

1. University of Applied sciences – Mechanical Engineering with graduation in Medical Technology 1996-2000
2. Design Engineer - Spierings Medical 2000 – 2001
3. Design Engineer - Handicare mobility 2002 – 2012
4. Project Leader – Novuqare Hospital Equipment 2012 – 2016
5. R&D manager – Dietz Power B.V. 2016 – so far

Start date of the trial: 09.10.2018
Clinical trial end date: 06.11.2018

The intended use of the medical device:

Powered wheelchair Sango M Slimline is a medical device designed to move people with reduced mobility to various causes.

Description of the medical device:

Sango M Slimline powered wheelchair designed to move people with reduced mobility with body weight up to 136 kg. The overall width of the chair is 530mm which allows users to manoeuvre through narrow spaces. The Sango M Slimline electric wheelchair is available in mid-wheel drive.

The electric wheelchair consists of a chassis, SEGO comfort seating system, seat, backrests, head restraints and foot and hand rests. The wheelchair (height, incline, ...) of the wheelchair can be adjusted according to the patient's specific requirements as instructed in the instruction manual. The wheelchair is controlled by the control system. The wheelchair is designed to move on a flat plane with ramp / slopes with step restrictions. The Sango M Slimline can be used for slopes with a gradient of ≤ 6˚ (10.5%).

European Standard:

EN 12184 (Electrically powered wheelchairs)

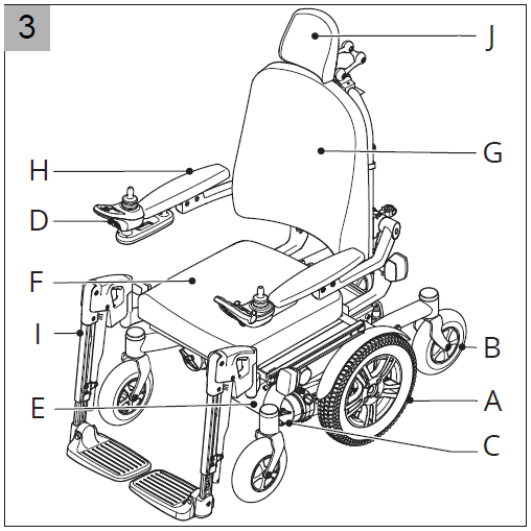
Technical parameters of the Sango M Slimline medical device:

Adjustable wheelchair parts:

A. Wheels (turning and pivoting)
B. Swing-away controller arm
C. Powered backrest adjustment
D. Powered tilt adjustment
E. Powered leg rests
F. Powered lift adjustment

A) Powered wheelchair Sango M Slimline

The Sango M Slimline has a mid-wheel drive.



A	Drive wheels
B	Castor Wheels
C	Freewheel switch
D	Control unit
E	Battery
F	Seat cushion
G	Backrest
H	Armrest
I	Leg rest
J	Headrest

Specifications:

Overall length including footrest: max. 1265 mm / min. 1070 mm
Total width: max. 700 mm / min. 530 mm
Total height without head restraints: max. 1340 mm / min. 1010 mm
Transport length incl. footrests: 1070 mm
Shipping width: 530 mm
Shipping height: 650 mm
Load capacity: 136 kg
Speed: 6 / 10 / 12,5 km/h
Seat plane angle: 0/4/8 °
Effective seat depth: max. 560 mm / min. 420 mm
Effective seat width: max. 500 mm / min. 420 mm
Seat cushion height at the front: max. 480 / min. 410 mm
Backrest angle: max. 120 ° / min. 90 °
Backrest height: max. 570 mm / min. 520 mm
Rotation radius: 420 mm
Clearance: 60 mm
Battery Dimensions: 60 Ah (225 x 136 x 177) mm

Safety instructions:

• Only trained personnel can use and operate the machine.
• Due to the presence of the sliding parts of the device, care must be taken to avoid injuries (pinching) mechanical parts of the device.
• Inadequate patient behaviour on a wheelchair (especially children) may cause injury to the patient on the edges of the device.
• Do not use the product in contravention of the operating instructions.
• Do not drive a wheelchair under the influence of addictive substances.
• Do not carry more than one person at a time on a wheelchair.
• Do not use the wheelchair outside the temperature range - 10 ° C to 50 ° C
• Do not use a wheelchair to carry heavy loads.
• Avoid contacting the wheelchair with sand or sea water.
• Avoid emergency stops on the slope / ramp.

Identification of safety related parameters:

The use of a wheelchair does not have therapeutic effects. Healthy materials are used in the manufacture of the medical device. When using the device, there is no energy transfer to the patient, no intake or dispense of substances, and no biological materials are processed. The composition is not sterile or sterilized. The instrument itself does not provide any interpreted conclusions. The wheelchair is not intended for use in conjunction with pharmaceuticals, it does not affect the health environment and is not sensitive to environmental influences. The wheelchair does not require special maintenance or calibration. Disposal and disposal must be carried out in compliance with the waste disposal regulations in force at the time of disposal. Incorrect handling can result in mechanical damage. The wheelchair has been assessed in terms of electromagnetic compatibility as fully compliant.

Hazard identification:

- Injury to the patient due to mechanical wheelchair destruction
- Destruction of the wheelchair due to too heavy weight
- Functional malfunction on the electric motor of the wheelchair
- Dangers resulting from inadequate patient behavior on a wheelchair
- Transmission of infection to the patient
- Insufficient maintenance and service specifications
- Insufficient maintenance
- Biological incompatibility of materials in contact with the patient
- Toxicity of materials in contact with the patient
- Use of a wheelchair contrary to the instructions for use
- Incorrect instructions for use
- Use improper instructions for use
- Loss of instructions for use
- Too complicated or unclear instructions for use
- Environmental damage when the wheelchair is out of service
- Failure to follow the instructions
- Insufficient warning of the operator against potential hazards
- Damage due to unclear marking of controls
- Breaking of the wheelchair carrier frame
- Broken or damaged wheel axle
- Failure of the control device
- Wheel jamming or deformation
- Seat height and slope incorrectly set

Risk management:

When determining the overall risk parameter according to the risk analysis based on the use of Annex D of CSN EN 14971: 2013, we have come to the conclusion that the Powered Wheelchair Sango medical device meets the safety parameters.

Risk reduction options:

- Follow the instructions for use.
- Observe statutory maintenance and service by the manufacturer.
- Thorough user training.

Evaluation of the medical device:

The medical device is suitable for use in its entirety. Based on the studied technical documentation, drawing documentation, instructions for use, risk analyses and known levels of quality of medical devices in this field, it can be stated that the device is suitable for use according to the intended purpose of use.

List of used literature:

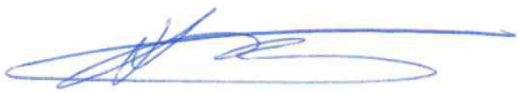
a) the documentation provided by the manufacturer:

Risk analysis
Instructions for use

Equivalence of the assessed medical device with other existing medical devices:

Medical devices used for comparison with the rated medical device:
Brand: Sunrise Medical
Trade mark: Salsa M² Mini
On the market Since: approx. 2014

Number of pages: 6
Date of preparation of the report: 9.11.2018
Place of report: Dietz Power BV, Helmond, The Netherlands
Signature:



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Dietz Power B.V.
D.G.J. van de Beek
Managing Director

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Dietz Power B.V.
Sjoerd Lintemans
R&D Manager