CLINICAL EVALUATION REPORT OF MEDICAL DEVICES N°CER/0010/2019/Rev.1

The clinical evaluation of the medical device described below was performed in agreement with the Council Directive 93/42/EEC concerning medical devices, the Act No. 268/2014 Coll., on medical devices and on changes in the Act No. 634/2004 Coll., on administrative fees, as amended, and the regulation No. 54/2015 Coll., Government Order on technical requirements for medical devices.

ELBUR Vertriebs GmbH	- Clinical evaluation report – Power wheelchair	March 2019

Name of the medical device:

Power wheelchair

Model of the medical device:

Viper, Viper Plus, Viper Lift

Riziková třída zdravotnického prostředku:

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Client - Manufacturer:

ELBUR VERTRIEBS GmbH
Askanierweg 12
32 429 Minden
Germany

Evaluator:

LACHMANN Hynek, M. D.

Working Address:

Department of Neurology, Second Faculty of Medicine, Charles University and Motol University Hospital, V Úvalu 84, Prague 5 Motol, 150 06 Czech Republic

Pavel Kolář´s Center of Physical Medicine, Walterovo náměstí 329/2, 158 00 Prague 5-Jinonice

Evaluator´s qualification and experience:

Education:

1990 - 1996 1st Medical School, Charles University, Prague

Graduation:

1996 M.D. /MUDr./

Specialization exam:

1999	Board certification: 1st degree from neurology
2000	Postgraduate certification: 2nd degree from neurology
2009	Certificate of Electromyography

Further education:

1998	Myoskeletal medicine training course
2000	Electromyography training course
2001	Evoked potentials training course

Training courses abroad:

2000	3 months - Clinical neurophysiology, Spine Center Schulthess Klinik, Zürich
2012	Upper and lower limb spasticity treatment using ultrasound control – prof. McArthur, Liverpool
2013	Cervical Dystonia Management: Col-Cap Concept – prof. Jost, Freiburg
2014/2015	Course Rehabilitation of spastic paresis A and B – J. M Gracies, M. Hoskovcová, R. Jech, Prague
2015	Advanced Ultrasound Guided Botulinum Toxin Injection Technique Training in Spasticity, Dr. Kocer – Switzerland
2016	Upper and lower limb anatomy course – cadaver practical's (advanced level based on ultrasound technique) – Dr. Druźdź, prof. Slawek, Poznan
2017	Ultrasound training – Euromusculus Prague, prof. Özcakar

Botulinumtoxin-A injections experience: Injecting from 2008. Using EMG control; From 2011 using ultrasound navigation or combination USG + EMG + stimulation.

Date of the beginning of the clinical evaluation: 20 February 2019

Date of completion of the clinical evaluation: 22 March 2019

Plan of the clinical evaluation:

- Evaluation of the medical device from the viewpoint of safety for its users and third persons providing health care in the scope of use indicated in the product documentation
- Verification of fitness of the medical device for the specified purpose of use and conformity with current clinical findings
- Evaluation of fitness for use in provision of health care in the scope of its use
- Evaluation of fitness for clinical use in the Czech Republic

The plan for clinical evaluation was created in agreement with the Council Directive 93/42/EEC concerning medical devices, the Act No. 268/2014 Coll., on medical devices and on changes in the Act No. 634/2004 Coll., on administrative fees, as amended later, and the regulation No. 54/2015 Coll., Government Order on technical requirements for medical devices.

Specified purpose of use of the medical device:
The electric powered wheelchair is a compensation aid designed for indoor and outdoor transport of the physically handicapped, persons with reduced mobility, persons with disability of lower limbs or various levels of paralysis.

Description of the medical device:
The electric wheelchair is provided with an upholstered seat and back rest, it has mechanically adjustable angles of the seat and the back rest, front and rear lights, removable and tilting foot rests, height-adjustable footboards, removable height- and width- adjustable side pieces, height-adjustable arm rests, springing of rear full wheels, stabilization wheels against overturning, safety belt and foldable control joystick (right/left). Optional accessories of the electric wheelchair include controls for an accompanying person. The Viper Plus model has also an adjustable upholstered head rest.

Technical parameters of the medical device for the model Viper:

The maximum loading capacity of the electric powered wheelchair is 160 kg. The height of the wheelchair is 100 cm, the width is 64 cm, the depth is 110 cm, the seat width is 40-56 cm, the seat depth is 47 cm, the seat height is 55 cm, the seat angle is -2-20°, the back rest angle is 90-150°, the front wheels diameter is 23 cm, the rear wheels diameter is 32 cm, the usual distance per charge is 20-30 km, the maximum distance per charge is 40 km, the maximum speed is 6 km/h, battery 2x12V, the engine power is 450 W and the weight of the powered wheelchair with the battery is 115 kg.

Technical parameters of the medical device for the model Viper Plus:

The maximum loading capacity of the electric powered wheelchair is 160 kg. The height of the wheelchair is 100 cm, the width is 67 cm, the depth is 110 cm, the seat width is 40,46 cm, the depth of the seat is 47 cm, the seat height is 55 cm, the seat angle is -2-20°, the back rest angle is 90-150°, the front wheels diameter is 25.4 cm, the rear wheels diameter is 35.5 cm, the usual distance per charge is 20-30 km, the maximum distance per charge is 40 km, the maximum speed is 6 km/h, battery 2x12V, the engine power is 450 W and the weight of the powered wheelchair with the battery is 130 kg.

Technical parameters of the medical device for the model Viper Plus:

The maximum loading capacity of the electric powered wheelchair is 160 kg. The height of the wheelchair is 100-130 cm, the width is 67 cm, the depth is 119-124 cm, the seat width is 40,46 cm, the depth of the seat is 45-50 cm, the seat height is 56-86 cm, the seat angle is -2-20°, the back rest angle is 90-150°, the front wheels diameter is 25.4 cm, the rear wheels diameter is 35.5 cm, the usual distance per charge is 20-30 km, the maximum distance per charge is 40 km, the maximum speed is 6 km/h, battery 2x12V, the engine power is 600 W and the weight of the powered wheelchair with the battery is 150 kg.

Safety instructions:

- Do not exceed the specified maximum loading capacity of the device.
- Do not use the product in conflict with the user´s manual
- Before using the wheelchair consult the attending physician.
- Before every ride check whether all adjustable parts are duly arrested.
- Do not sit on the electric wheelchair during transport (by car, bus, train etc.).
- Adapt the riding style and speed to your experience and ability and, particularly, to the quality and profile of the ground (rough surface, barriers, curves, slope, wet surface, etc.).
- Do not ride the wheelchair on a soft ground (grass, sand, mud…).
- Do not use the electric wheelchair on a slippery, hilly or very smooth surface
- Do not overcome high barriers or steep slopes.
- Be careful when turning on an inclined ground; the gradient should not be more than 8°
- If the bend is too sharp make sure to reduce the riding speed.
- Do not ride the electric wheelchair if the rear stabilization wheels are damaged or removed
- Do not expose the electric wheelchair to wet environment and do not use it in rain
- The electric wheelchair shall be controlled by one person only
- Switch off the power before getting on/off the wheelchair
- Keep your feet on the foot rests and make sure to have sufficient space around you
- The footboard is designed only as support for the lower limbs and you should never step on it.
- Pay attention when crossing roads and always use pedestrian crossings
- Never switch off electromagnetic brakes (yellow turn buttons) when standing on an inclined surface

- When riding in proximity of roads make sure to comply with the traffic code
- Never exceed the maximum speed of the electric wheelchair
- Do not transport bulky or heavy items on the wheelchair
- Do not hang a backpack or a bag on the back rest
- Do not ride on steps or moving stairways

Identification of safety-related parameters:

The use of the electric wheelchair has no therapeutic effects. The medical device is made of safe, non-toxic and biological materials. When using the device there is no transfer of energy to the patient, no intake or release of substances and no biological materials are processed. The device is not sterile or sterilized. The device alone does not provide any interpretable conclusions. The electric wheelchair is not designed to be used in combination with medicines, it does not influence the sanitary environment and it is not sensitive to environmental effects. The electric wheelchair does not require any special maintenance or calibration. The product supply does not include any software. Retirement and liquidation shall be made in agreement with regulations for waste disposal in effect at the time of the liquidation. The device is connected to a power source. Inappropriate handling may result in mechanical damage of the device.

Identification of risks:

- Patient´s injury as a result of mechanical destruction of the electric wheelchair
- Destruction of the electric wheelchair as a result of excessive loading
- Patient´s injury caused by hitting obtuse edges of the electric wheelchair
- Hazards resulting from inadequate conduct of the client (e.g. mentally handicapped)
- Insufficient specification of maintenance and servicing
- Insufficient maintenance
- Biological incompatibility of materials in contact with patient´s skin

- Use of the electric wheelchair in conflict with the user´s manual
- Incorrect user´s manual
- Use of an incorrect user´s manual
- Loss of the user´s manual
- Too complicated or unclear user´s manual
- Risk to the environment after the electric wheelchair is retired
- Non-observation of the user´s manual

Risk management:

When determining the overall risk parameter resulting from the risk analysis we have come to the conclusion that the electric wheelchair meets the safety parameters.

Negligible risks:

- Insufficient specification of maintenance and servicing
- Risk to the user as a result of non-observation of the user´s manual

Possibilities to reduce risks:

- Follow the user´s manual
- Perform the prescribed maintenance and servicing based on the long-term experience with operation of similar devices as specified in the user´s manual

Evaluation of the medical device:

The medical device is fit for the use in the full scope. Based on the reviewed documentation, user´s manual, risk analysis and the known quality level of medical devices in this field it is possible to conclude that the device is fit to be used for the specified purpose. The electric powered wheelchair is a compensation aid designed for indoor and outdoor transport of the physically handicapped, persons with reduced mobility, persons with disability of lower limbs or various levels of paralysis.

List of references:

a) Documentation provided by the manufacturer:

Risk analysis

User´s manual

Technical documentation

b) Specialized literature

Adjustable height anti-tip wheels for a power wheelchair, Walter A. Watkins, 2001, United States Patent, US6533306B2

Stop for an anti-tip wheel for a wheelchair, Daniel Z. Zhou, 2004, United States Patent, US7222881B1

Power wheelchair, Walter Schaffner, 2003, United States Patent, US20040188152A1

Power wheelchair, James Mulhern, Gerald White, Mark Smith, Charles Martis, 2002, United States Patent, US20030201632A1

Electric mid-wheel drive wheelchair, Mehdi Mirzaie, 2010, United States Patent, US8851214B2

Anti-tip system for wheelchairs, James Mulhern, Ronald Levi, 2004, United States Patent, US20050077714A1

Equivalence of the evaluated medical device with other previously existing medical devices:

The proof of equivalence of the evaluated medical device with another medical device has been determined based on three independent reviewed areas. The equivalence of the medical device was evaluated based on the clinical, technical and biological aspects.

The clinical aspect of equivalence included evaluation of use of the evaluated medical device in the same environment subject to the condition of the same

purpose of the use for the same problematic group of patients as the compared medical device.

The technical aspect of equivalence included evaluation of technical parameters, similar appearance, properties, specifications and possible similar risks as the compared medical device.

The biological aspect of equivalence included evaluation of use of the same or similar materials that are in contact with human body. Further, biological safety of the material was evaluated in relation to the compared medical device.

Based on the comparison of the individual medical devices and evaluation of the clinical, technical and biological aspects, consideration of all potential differences or determination of risks, the medical device has been found equivalent with the medical devices listed below and therefore we consider it an equivalent medical device.

Medical devices used for comparison with the evaluated medical device:

- electric wheelchair Faster Clou 9.500 by MEYRA
- electric wheelchair iChair MC Basic 1.609 by MEYRA
- electric wheelchair iChair MC1 1.610 by MEYRA
- electric wheelchair iChair MC2 1.611 by MEYRA
- electric wheelchair iChair MC2 S 1.616 by MEYRA
- electric wheelchair iChair MC3 1.612 by MEYRA
- electric wheelchair iChair MC3 Lift 1.612-27 by MEYRA
- electric wheelchair iChair MC Front 1.613 by MEYRA
- electric wheelchair REHAB 4220 X by MEYRA
- electric power wheelchair DINGO made by PATRON Bohemia a.s.
- electric wheelchair PANTHER made by PATRON Bohemia a.s.

Content of the final report:

Name of the evaluated medical device

Risk class of the medical device

Identification of the client - manufacturer

Identification of the evaluator

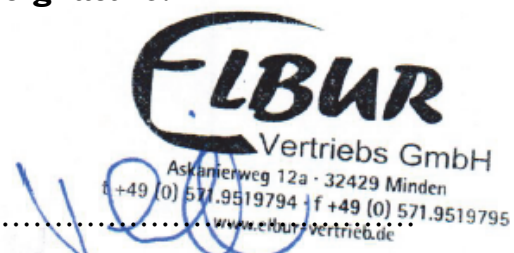
Qualification and experience of the evaluator
Dates of beginning and completion of the clinical evaluation
Plan of evaluation of the medical device
Determination of the purpose of use of the medical device
Description of the medical device
Technical parameters of the medical device
Safety instructions
Identification of safety related parameters
Risk management
Evaluation of the medical device
List of references
Equivalence of the evaluated medical device with previously existing medical devices
Content of the final report
Number of pages
Date of report development
Place of report development
Signature of the client –manufacturer
Signature of the evaluator

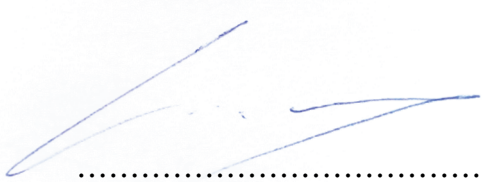
Number of pages: 11

Date of report development: 27 March 2019

Place of report development: Prague

Signature:





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ELBUR VERTRIEBS GmbH	**LACHMANN Hynek, M. D.**
Client - manufacturer	Evaluator