Electrical powered wheelchairs – Moto

Analysis conclusion
After finished analysis, HEPRO AS concludes the following for the analysed product:

By use in accordance with the Users Instructions or by probable user wrong-doings, it is not defined to be of any danger for the user or the environment that demands further actions.

Products included in the risk analysis

Item number	*Model*
15004	Moto

1. Risk analysis dimension

The analysis process includes specific demands on the leadership and the participants in the project. Hepros quality system (QA) that is certified in accordance with NS-EN ISO 9001:2000, has the necessary routines for attention.

2. Terms and definitions

The analysis uses the standards definitions as described in section 2.1 – 2.22.

3. General demands to direction of risk analysis

3.1 National or regional regulated demands

Independent from national or regional demands, section 3.3 and 3.4 are in force.

3.2 Leadership defined process for risk analysis

Responsibility is covered by the routines described in the QA-system.

During the process the following areas are covered:

- Risk analysis
- Risk evaluation
- Risk control
- Post production information and experience
-

3.3 Leadership responsibility

Policy for risk analysis and basic factors:

- The product shall satisfy the demands the international standards of requirements that "Rikstrygdeverket" demands for contract acceptance.
- Hepro ensures resources with necessary competence for carrying out the risk analysis.
- Hepro ensures correct competence during production of the product, in order to make sure that the product is presented with the characteristics that were basis for the risk analysis.
- Every change, large or small, shall be evaluated against the current risk analysis before the change is approved and executed.
- Special adaptation must be considered particularly against the risk analysis in order to ensure that a rebuilding does not lead to unintended risk for the user or the environments.

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3.4 Approval of personnel
The QA systems demands on education and qualification of personnel covers this demand.

3.5 Plan for risk analysis
A particular plan is not worked out but analysis is included into defined activities such as design, construction and production. The finished product shall be approved in accordance with relevant international standards before it is released to ordinary production and marked deliverance.

3.6 Documentation of risk analysis
All risk analysis based upon NS-EN ISO 14971 are worked out based upon this documents template, and store on separate area on Hepros server. New evaluation of the existing risk analysis will be carried out by product changes or approval in accordance with new standards or customer defined demands.

4.0 Risk analysis

4.1 Basis for risk analysis
Based upon the following the risk analysis is executed:

a)	Product description:	Moto is built on a welded steel frame which has fixing point for wheels, motors, batteries, lifting unit and plastic covers. The lifting unit is cone shaped in the end where the seat unit is fixed. The seat unit consists of seat frame, seat cushion, backrest cushion and armrests. The controller unit is fixed to the right armrest. Controller fixation bracket for left side mounting is accessory. Controller – VSI has all operations for driving and seat lifting regulation built-in. The controller is delivered pre-programmed. A particular programmer is needed for the programming. Change of the programming shall primarily be executed by the supplier (HEPRO AS). Changing of the programming executed by others must be approved by the supplier. Programming on special executed products is executed by the supplier upon delivery. **MOTO HAS:** • Electrically adjustable seat height • Angle adjustable seat • Adjustable armrests –height/width • Height adjustable leg support with angle adjustable foot plate • Height- and angle adjustable backrest • Electrical motor drive and parking brake on rear wheels • Joystick steering. The console can be height and length adjusted, and removed backwards. It is locked in user position with "snap-lock". • Anti-puncture wheels
b)	Responsible for the analysis:	Technical Manager, Einar Øines
c)	Execution date:	30.04.2006

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4.2 Description of assumptions for use and identification of aspects related to security.

Assumptions for use:
This is described in User Instructions for the product, particularly under the sections for *safety regulations and warning*.

Tests in accordance with the following standards are carried out and passed though accredited test laboratories. (Test reports or confirmations are enclosed to the RTV-tender).

Standard	***Name***
NS-EN 12182	" Technical aids for disabled persons - General requirements and test methods".
NS-EN 12184	"Electrically powered wheelchairs, scooters and their chargers – Requirements and test methods".
NS-EN 1021-1	"Furniture – Assessment of the ignitability of upholstered furniture – part 1: Ignition source: smouldering cigarette".
NS-EN 1021-2	"Furniture – Assessment of the ignitability of upholstered furniture – part 1: Ignition source: match flame equivalent".
93/42/EØF	Equipment class I CE marked

Examination of Annex A (A2.1 – A2.28) gives the following terms regarding security, and will be analysed further in this report.

Ref	Terms for further analysis in section 4.3 and 4.4:
A 2.1	Description of correct use appears in the Users Instructions.
A 2.2	The products are for inn-door use and are in direct contact with the user during use.
A 2.3	Seat- and backrest cushions are of polyurethane foam covered with 100% trevira upholstery.
A 2.4	Not relevant.
A 2.5	Not relevant.
A 2.6	Not relevant.
A 2.7	Not relevant.
A 2.8	Cleaning executed by the user is described in the Users Instructions.
A 2.9	Not relevant.
A 2.10	Not relevant.
A 2.11	Not relevant.
A 2.12	Not relevant.
A 2.13	The wheelchairs have 2x 12V batteries that give an effective voltage of 24V. The batteries are secured by a main fuse. The digital controller has built-in protective circuits and controls the effect from the motor and other functionalities.
A 2.14	Electrical security. EMC and inflammability.
A 2.15	Electrical security and EMC.
A 2.16	Not relevant.
A 2.17	Necessary maintenance is described in the User Instructions and Technical Documentation.
A 2.18	Digital programmable controller.
A 2.19	Not relevant.
A 2.20	The seat unit is ergonomically shaped, and may loose its qualities after loge time of fuse or through wear and tear.
A 2.21	User weight and use is stated in the Users Instructions.
A 2.22	Lifetime depends on user weight and user environment/conditions.
A 2.23	The product is constructed and approved for 1 person.
A 2.24	Special waste by destruction is: Controller, cables and batteries. The remaining is metal, PUR-foam and plastic.
A 2.25	Necessary training is taken care of in the Users Instructions.

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Ref	Terms for further analysis in section 4.3 and 4.4:
A 2.26	The production processes are always evaluated against possible risk consequences before change or implementing of a process.
A 2.27.1	The products have accessories with belonging mounting instructions.
A 2.27.2	Described in "Technical documentation".
A 2.27.3	Display and warning lamps give necessary information, see "Users Instructions".
A 2.27.4	Not relevant.
A 2.28	The product is described in section 4.1 a).

4.3 - 4.4 are combined and taken care of in the table below.

Ref	4.3 Identification of known and predictable risk	4.4 Evaluation of consequences
A 2.1	Use without training or not in accordance with the user manual.	Violation of critical safety regulations and warnings.
A 2.2	Skin contact with Trevira CS and rubber materials.	Allergic reactions.
A 2.3	The products are constructed by well known materials, components and upholsteries.	Generally increasing allergic tendencies in the population may give reactions from materials that the user gets in touch with.
A 2.8	Cleaning is regarded as necessary preventive maintenance to uphold functionality.	By lack of cleaning, the product may work insufficient, and seat comfort and ergonomic characteristics may be reduced.
A 2.13	Water spoil during cleaning may penetrate the controller if it has external damages.	May short-circuit the electronic board and cause permanent damage on the electronics.
A 2.14	May be affected by external electronics.	The user lose "the steering" of the product.
A 2.15	May affect other electronics within the environment.	Operation of the product lead activation of other electronically devices.
A 2.17	The products consist of many movable parts and presume maintenance as described in order to work properly.	The complete product looses its functionality or operation possibility.
A 2.18	Change of approved controller programming.	The product does not satisfy the approved safety demands.
A 2.20	Long time use may lead to cushions with reduced pressure distribution effect.	Reduced pressure distribution may cause unnecessary strain to the body.
A 2.21	Stability and security presume that the given user weight is not exceeded. The product is used in conflict with warning and safety information.	Breakage may occur on the product. The wheelchair may tip over as a consequence of larger weight than approved. Over turn may cause user damages.
A 2.22	The life-time assumes that the user weight is not exceeded and that the product is used under the circumstances that is described and tested.	Abnormal mechanical wear and tear on movable parts is related to weigh. The environment the product is used in affects components and surface treatment.
A 2.23	The product is constructed, produced and tested for on person.	Increased wear and tear caused by excess weight. Tip over risk and risk of person damage caused reduced stability.
A 2.24	No particular risk.	Consequences are of environmental character and not a risk for the user or the product.
A 2.25	The product is delivered from the HMS without giving necessary training to the user.	Use in conflict with the user instructions is always connected with risk for the user, and especially regarding excess weight and stability.
	4.3 Identification of known and predictable	4.4 Evaluation of consequences

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Ref	risk	
A 2.26	No particular. The QA-system takes care of this in accordance with the scale of the change.	Taken care of by QA instructions.
A 2.27.1	Risk is wrong mounting or mounted on product not supposed for.	Depend on the function of the accessory.
A 2.27.2	Changing of the programming on the digital controller.	The product is not safe, and herby not in accordance with the approval.
A 2.27.3	No particular risk.	None.
A 2.28	The following risks are regarded relevant related to the products use and operation: 1. Use outside of the use area. 2. Over tip danger if used in high speed and the seat unit in high position. 3. Backward tip danger. 4. Fire damages.	1. Wrong use may cause damages on user or the product. 2. The speed must be adapted to the driving. 3. Carelessness by obstacle force. The product is secured by anti-tip wheels. 4. Cigarette or cigar smoking.

5 Risk evaluation

Based upon the table above (4.3 and 4.4) the following evaluation is done:

Ref	Evaluation
A 2.1	Risk regarded not relevant, necessary information and guidance are included in the delivery responsibility.
A 2.2	Risk regarded relevant. Skilled personnel must take care of this together with the user if the user has allergic problems.
A 2.3	Risk regarded relevant. Skilled personnel must take care of this together with the user if the user has allergic problems.
A 2.8	Risk regarded not relevant since the cleaning information are included in the delivery responsibility.
A 2.13	Risk regarded not relevant. Shall be taken care of by the user report responsibility by damage or by suspicion.
A 2.14	Risk regarded not relevant. The products are tested for EMC.
A 2.15	Risk regarded Not relevant. The products are tested for EMR.
A 2.17	Risk regarded relevant. The user's maintenance responsibility is taken care of by through the official skilled persons training responsibility and is described in the users instructions.
A 2.18	Risk regarded as minimal. Necessary programming equipment is available only for qualified personnel and external service representatives.
A 2.20	Risk regarded relevant for users who stays in the chair for long periods. Skilled personnel must take care of this aspect if the user is disposed for problems.
A 2.21	Risk regarded relevant. Skilled personnel and HMS must ensure that there is conformity between the products performances, limitations and the users needs. This is particularly regarding weight limitations and areas of use. The supplier (HEPRO AS) has few possibilities to influence wrong use of the products.
A 2.22	Risk regarded relevant. Skilled personnel and HMS must ensure that there is conformity between the products performances, limitations and the users needs. This is particularly regarding weight limitations and areas of use. The supplier (HEPRO AS) has few possibilities to influence wrong use of the products.
A 2.23	The risk is regarded as minimal since the seat unit is designed for 1 person.
A 2.24	Risk regarded not relevant.
A 2.25	Risk regarded relevant. All products demand training and imparted knowledge about where to find information about critical product use.
Ref	**Evaluation**
A 2.26	Risk regarded not relevant.
A 2.27.1	Risk regarded minimal. HMS that owns the product is always the one that order accessories. HMS has in their control that qualified personnel perform the mounting of the accessories.

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A 2.27.2	Risk regarded minimal. Technical papers, information and training take care of this.
A 2.27.3	Risk is minimal. This is an essential element in the training that is HMS responsibility.
A 2.28	As supplier we regard the risk as properly taken care of through development and product testing, combined with the specifications in the users instructions.

6. Need for repeated risk evaluation

We hereby conclude that section 5 Risk evaluation does not need repeated risk evaluation and the analysis is ended and fulfilled.

(Improvement process and repeated evaluation are carried through by following the standards section 6.1 – 6.7.)

7. Total remaining risk evaluation

No known circumstances require new risk analysis process.

8. Risk analysis report

The risk analysis documentation is covered with this report.

9. Re-examination and follow-up of the risk analysis report

The risk analysis will be re-examined by every production change, change of use conditions and work processes where it's demanded or regarded as necessary.

Report preparation and approval

This report is worked out in accordance with the demands in the standard and the intention to take care of the safety for the user and its environment.

Rognan 30.04.2006

Einar Øines
Technical Manager