

Manufacturer  
Medema A/S  
Enggårdvej 7  
DK-7400 Herning

Herning, 7. October 2020

## EC – Declaration of conformity Mini Crosser model-X1

Medema-A/S declares on our sole responsibility that the product range mentioned below are manufactured in accordance with our incorporated standards and are in conformity with the following directives and standards if they are used according to our instructions:

Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices.

EN 12184:2014 Electrically powered wheelchairs, scooters and their chargers - Requirements and test methods.

Directive 2006/42/EC of the European Parliament and of the Council of 17 May 2006 on machinery, and amending Directive 95/16/EC.

Directive 2011/65/EU of the European Parliament and of the council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment.

EN 50581:2012 Technical documentation for the assessment of electrical and electronic products with respect to the restriction of hazardous substances.

ISO 14971:2012 Medical devices – Application of risk management to medical devices.

Type of use : Transporting walking disabled people  
Risk Class : 1 according to rule 1.

The product range in the **Mini Crosser model-X1** includes the following items

| Product name                | Basic UDI-DI         |
|-----------------------------|----------------------|
| Mini Crosser X1 3W 10kmh    | 5707299MCX1-3W105V   |
| Mini Crosser X1 3W 13kmh    | 5707299MCX1-3W1363   |
| Mini Crosser X1 3W 15kmh    | 5707299MCX1-3W1567   |
| Mini Crosser X1 4W 10kmh    | 5707299MCX1-4W1064   |
| Mini Crosser X1 4W 13kmh    | 5707299MCX1-4W136A   |
| Mini Crosser X1 4W 15kmh    | 5707299MCX1-4W156E   |
| Mini Crosser X1 HD 4W 10kmh | 5707299MCX1-4WHD1057 |
| Mini Crosser X1 CAB 10 kmh  | 5707299MCX1-CAB10JR  |
| Mini Crosser X1 CAB 13 kmh  | 5707299MCX1-CAB13JX  |
| Mini Crosser X1 CAB 15 kmh  | 5707299MCX1-CAB15K3  |

Medema-A/S



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**Klaus Smedegaard**  
R&D Manager

Medema A/S

Enggårdvej 7  
Snejbjerg  
7400 Herning

CVR/VAT: DK 51 89 27 12  
SRN: DK-MF-000000981

Phone: 70 10 17 55

info@medema.com  
www.medema.com



medemagruppen