this

DECLARATION OF CONFORMITY

is provided under the sole responsibility of the manufacturer:

Lewis Seating Systems B.V.

Willem Vleertmanstraat 23a, 7575 EC Oldenzaal, Nederland

Declares that the following medical device:

Registered trade name	Lewis zitorthese
Product codes	MON, DOB
Product type	Seat orthosis, including accessories
Risk Class	Class 1
Basic UDI-DI	87202991354LEWIS2007WL
SRN	NL-MF-000001485

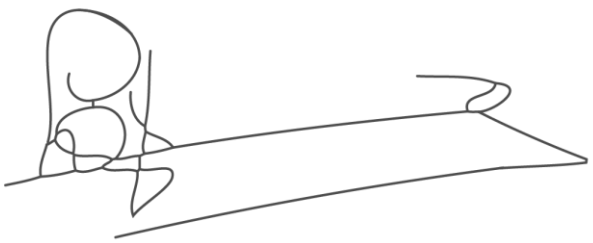
To which this declaration refers in compliance with the essnetial requirements of the following directive:

Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017

And are in accordance with the following European Standards:

NEN-EN-ISO 7176-15	Wheelchairs part 15 – Requirements for information disclosure, documentation and labelling
NEN-EN-1041 + A1	Information supplied by the manufacturer of medical devices
NEN-EN 14971	Medical devices – Application of risk management to medical devices (corrected and reprinted 2012-07) (ISO 14971:2007-03, IDT)
NEN-EN-ISO 7176-19	Wheelchairs part 19 – Wheeled mobility devices for use as seats in motor vehicles
NEN-EN-ISO 10993-1	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
EN 1021-2	Furniture - Assessment of the ignitability of upholstered furniture - Part 2: Ignition source match flame equivalent

Signed on behalf of Lewis Seating Systems



Dhr. A.G.M Huttenhuis
Managing Directeur

Date: 11 March 2021

Lewis
SEATING SYSTEMS

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