EU DECLARATION OF CONFORMITY

We,

Drive DeVilbiss Healthcare Ltd,
Sidhil Business Park,
Holmfield,
Halifax,
West Yorkshire,
HX2 9TN,
UK

Hereby declare under our sole responsibility that the devices specified are in conformity with:

REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC.

EU authorised representative: Advena Ltd., Tower Business Centre, 2nd Flr., Tower Street, Swatar, BKR 4013, Malta
SRN: MT-AR-000000234

General product name: Static mattress range

Product variants:

• MAT10BE	MAT10
• MAT20BE	MAT20
• MAT/SOFT	Softrest
• MAT/SOFT/CON	Softrest Contour
• MAT/SOFT/CON/190/120	Softrest Contour (1900L X 1200W)
• MAT/SOFT/PERM	Permaflex ST
• MAT/SOFT/VE	Softrest VE
• MAT/ACCL/MF	Memaflex
• MAT/ACCL/PERM/HSF	Permaflex HSF
• MAT/ACCL/PERM/PLUS	Permaflex Plus
• MAT/ACCL/VE/W	Acclaim VE
• MAT/ACCL/VE/W/WHITE	Acclaim VE White
• MAT/ACCL/AIR/VE	Air Layer
• MAT/SOFT/PAD	Softrest Overlay
• MAT/SOFT/PAD/D	Softrest Overlay Double

GMDN code: 63237

BASIC UDI-DI: 50557857SPC001M9

Intended purpose: The intended purpose of the mattress is to support the weight of the patient whilst sleeping and / or resting and to assist the user with pressure distribution as part of an overall plan of care.

Risk class: Medical device class I as defined by rule 1 of Annex VIII of EU 2017/745.

Conformity assessment procedure: Issuing of the declaration of conformity in accordance with Article 19 after drawing up the technical documentation laid out in Annexes II and III of regulation EU 2017/745

The medical devices to which this declaration relates are in compliance with the following standards:

EN ISO 20342-1:2019	Assistive products for tissue integrity when lying down – Part 1: General requirements
EN 12182:2012	Assistive products for persons with disability. General requirements and test methods
BS 7177:2008+A1:2011	Specification for resistance to ignition of mattresses, mattress pads, divans and bed bases (medium hazard)
EN ISO 14971:2012	Medical devices- Application of risk management to medical devices
EN 62366:2008+A1:2015	Medical devices – Application of usability engineering to medical devices
EN ISO 15223-1:2016	Medical devices- Symbols to be used with medical device labels, labelling and information to be supplied
EN 1041:2008+A1:2013	Information supplied by the manufacturer of medical devices.

Signed for and on behalf of Drive DeVilbiss Healthcare Ltd.

Name: Mr Alastair Fry
Title: Head of international regulatory affairs and compliance
Date of Issue: 8th June 2021
Place of Issue: Drive DeVilbiss Healthcare Ltd, Halifax, HX2 9TN, UK