

EC DECLARATION OF CONFORMITY

Company Name	Recticel Limited Company No. 00665376
Company Address	Bluebell Close Clover Nook Industrial Park Alfreton Derbyshire DE55 4RD
Product	Product name: Modular Cushion FFC21_(N85419) Intended use: As a cushion suitable for wheelchair and day care chairs where, for example, pressure care patient support surface and waterproof covers are required.
Risk Class	Class I
Conformity Assessment Route	Recticel Limited uses the following procedures for the CE-labelling of their products according to the Medical Device Directive 93/42/EEC. Class I non-sterile, without measuring function: in accordance with 93/42/EEC Medical Devices.
General Description	Static pressure distribution flexible smooth surface cushion for wheelchair users. Primagel cushion uses CMHR foam with a profiled upper surface to increase pressure distribution encasing a silicone gel sac.

This declaration of conformity is issued under the sole responsibility of Recticel Limited. We hereby declare that the medical device specified above meets the provision of the Medical Device Directive 93/42/EEC for medical devices. All supporting documentation is retained at the premises of the manufacturer.

SIGNATURE



PLACE AND DATE OF ISSUE

12.08.2021

NAME: Tammy Sharp

FUNCTION: Product Manager

FORM NAME: MDD Documentation – Declaration of Conformity – FFC21