

DECLARATION OF CONFORMITY

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Declaration of Conformity Annex VII EU Directive 93/42/EEC
UKCA to supersede CE Conformity Mark

We, as company: Harvest Healthcare Ltd
Sheaf House
Bradmarsh Way
Bradmarsh Business Park
Rotherham, S60 1BW

Authorised Representative: European Healthcare & Device Solutions Ltd.
Stratton House, Bishopstown Road, Cork T12 Y9TC, Ireland
SRN: TBC

Confirm on our own behalf that the medical product:

Please see the Static Cushions list on the next page.

Risk Class: I

SRN: TBC

complies with all applicable requirements in Appendix I of the EU directive 93/42/EEC
The following compliance evaluation process was applied: Annex VII
EU legislation for this type of product covers all safety, health and environmental requirements.

Modifying this product without consultation with Harvest Healthcare Ltd will invalidate this declaration of conformity.

This declaration of conformity is issued under the sole responsibility of Harvest Healthcare.

Notified Body: TBC



Product Development and Quality Manager
Rotherham, 28.01.2021

This document is valid for 4 years after the date of the signature.

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Here is the list of the Static Cushions.

Community Modular Foam	HFC121	UDI: 5060517530303
Community Modular Foam (Large)	HFC116	UDI: 5060517530310
Prime Comfort Plus Vico Top	HFC129.01	UDI: 5060517532147
Prime Comfort Visco Top	HFC129	UDI: 5060517530341
Prime Comfort Visco Top (Large)	HFC123	UDI: 5060517530358
Reflect	HFC130	UDI: 5060517530402
Reflect Extra	HFC130.EX	UDI: 5060517531065