



## **Declaration of Conformity**

**Name & Address of the Manufacturer:** Trulife Limited,  
Airtown Road,  
Tallaght,  
Dublin 24,  
Ireland

**Single Registration Number:** IE-MF-000003108

**Competent Authority:** The Health Products Regulatory Authority,  
Block A, Kevin O'Malley House,  
Earlsfort Centre,  
Earlsfort Terrace,  
Dublin 2, D02 XP77  
Ireland

**Name of Device(s):** Wheelchair Cushion Relax Range

**Reference Code:** See Annex I attached

**Basic UDI-DI:** 00643293RelaxU4

**Intended Use:** The relax range of cushions are designed to provide support, weight distribution and pressure distribution for wheelchair users and people of restricted mobility who spend extended periods of time in a seated position.

**Classification:** Class I

**Rule:** Rule 1 Annex VIII – MDR 2017/745

We hereby declare, under our sole responsibility, that the below product groups are Class 1 Medical Devices registered in Ireland and are in conformity with the European Medical Device Regulations 2017/745 and relevant standards (See Annex II attached).

**Approved by:**



Eoin Redmond  
Operations Manager  
(On behalf of Trulife)

**Date:**

15/03/2022

**Place of Issue:**

AIRTON RD, DUBLIN, IRELAND

**Expiry Date:** 15/03/2023

### Annex I

Item No/Product Code	Name	Description
CC002	CoolCell/ Gelcell Spacer Fabric Cover	
CC004	Relax CoolCell Standard Black Cover	
CC005	Relax CoolCell G2 Standard Black Cover	
DC003	Duogel Standard Black Cover	
DC009	Relax Duogel Mesh Cover	
DWC003	Duogel Wipeable Cover	
EC004	Relax Wipedown Easy Cushion Cover	
ECH005	Relax Easy High Profile Wipedown Black Outer Cover	
GC004	Relax Gelcell Cover	
GC005	Relax Gelcell G2 Cover	
TC001	Relax Trio Cushion Cover	
RC002-1616	Relax CoolCell Cushion with Spacer Cover	16x16in
RC002-1717	Relax CoolCell Cushion with Spacer Cover	17x17in
RC002-1816	Relax CoolCell Cushion with Spacer Cover	18x16in
RC002-1818	Relax CoolCell Cushion with Spacer Cover	18x18in
RC004-1616	Relax CoolCell Cushion with Standard Black Cover	16x16in
RC004-1717	Relax CoolCell Cushion with Standard Black Cover	17x17in
RC004-1816	Relax CoolCell Cushion with Standard Black Cover	18x16in
RC004-1818	Relax CoolCell Cushion with Standard Black Cover	18x18in
RD003-1414	Relax Duogel Cushion	14x14in
RD003-1514	Relax Duogel Cushion	15x14x3in
RD003-1517	Relax Duogel Cushion	15x17x3in
RD003-1518	Relax Duogel Cushion	15x18in
RD003-1616	Relax Duogel Cushion	16x16x3in
RD003-1618	Relax Duogel Cushion	16x18x3in
RD003-1620	Relax Duogel Cushion	16x20x3in
RD003-1716	Relax Duogel Cushion	17x16x3in
RD003-1717	Relax Duogel Cushion	17x17x3in
RD003-1718	Relax Duogel Cushion	17x18x3in
RD003-1719	Relax Duogel Cushion	17x19in
RD003-1720	Relax Duogel Cushion	17x20x3in
RD003-1816	Relax Duogel Cushion	18x16x3in
RD003-1818	Relax Duogel Cushion	18x18X3in
RD003-1820	Relax Duogel Cushion	18x20x3in
RD003-1916	Relax Duogel Cushion	19x16x3in



### Annex I (cont'd)

Item No/Product Code	Name	Description
RD003-1918	Relax Duogel Cushion	19x18x3in
RD003-1920	Relax Duogel Cushion	19x20x3in
RD003-2016	Relax Duogel Cushion	20x16x3in
RD003-2018	Relax Duogel Cushion	20x18x3in
RD003-2020	Relax Duogel Cushion	20x20x3in
RD003-2218	Relax Duogel Cushion	22x18x3in
RD003-2418	Relax Duogel Cushion	24x18x3in
RD006-1414	Relax Duogel With Wipeable Cover	14x14x3in
RD006-1514	Relax Duogel With Wipeable Cover	15x14x3in
RD006-1517	Relax Duogel With Wipeable Cover	15x17in
RD006-1616	Relax Duogel With Wipeable Cover	16x16x3in
RD006-1618	Relax Duogel With Wipeable Cover	16x18x3in
RD006-1717	Relax Duogel With Wipeable Cover	17x17x3in
RD006-1719	Relax Duogel With Wipeable Cover	17x19in
RD006-1816	Relax Duogel With Wipeable Cover	18x16x3in
RD006-1818	Relax Duogel With Wipeable Cover	18x18x3in
RD006-1820	Relax Duogel With Wipeable Cover	18x20x3in
RD006-2018	Relax Duogel With Wipeable Cover	20x18x3in
RD006-2020	Relax Duogel With Wipeable Cover	20x20in
RD006-2218	Relax Duogel With Wipeable Cover	22x18x3in
RD006-2418	Relax Duogel With Wipeable Cover	24x18x3in
RDP003-1616	Duo-Profile with Standard Black Cover	40x40x8cm
RDP003-1717	Duo-Profile with Standard Black Cover	43x43x8cm
RDP003-1816	Duo-Profile with Standard Black Cover	45x40x8cm
RDP003-1818	Duo-Profile with Standard Black Cover	45x45x8cm
RDP003-2018	Duo-Profile with Standard Black Cover	50x45x8cm
RDP006-1616	Duo-Profile with Wipeable Cover	40x40x8cm
RDP006-1717	Duo-Profile with Wipeable Cover	43x43x8cm
RDP006-1816	Duo-Profile with Wipeable Cover	45x40x8cm
RDP006-1818	Duo-Profile with Wipeable Cover	45x45x8cm
RDP006-2018	Duo-Profile with Wipeable Cover	50x45x8cm
RDP009-1616	Duo-Profile with Mesh/Spacer Cover	40x40x8cm
RDP009-1618	Duo-Profile with Mesh/Spacer Cover	40x45x8cm
RDP009-1716	Duo-Profile with Mesh/Spacer Cover	43x40x8cm
RDP009-1717	Duo-Profile with Mesh/Spacer Cover	43x43x8cm
RDP009-1816	Duo-Profile with Mesh/Spacer Cover	45x40x8cm
RDP009-1818	Duo-Profile with Mesh/Spacer Cover	45x45x8cm
RE005-1416	Relax Easy Cushion	14x16x2in
RE005-1418	Relax Easy Cushion	14x18x2in

RE005-1616	Relax Easy Cushion	16x16x2in
RE005-1717	Relax Easy Cushion	17x17x2in
RE005-1816	Relax Easy Cushion	18x16x2in
RE005-1818	Relax Easy Cushion	18x18x2in
RE005-1820	Relax Easy Cushion	18x20x2in
RE005-2020	Relax Easy Cushion	20x20x2in
RE005-2218	Relax Easy Cushion	22x18x2in
REH005-1616	Relax Easy High Profile Cushion	40x40x8.5cm
REH005-1717	Relax Easy High Profile Cushion	43x43x8.5cm
REH005-1816	Relax Easy High Profile Cushion	45x40x8.5cm
REH005-1818	Relax Easy High Profile Cushion	45x45x8.5cm
REH005-1820	Relax Easy High Profile Cushion	45x50x8.5cm
REH005-2020	Relax Easy High Profile Cushion	50x50x8.5cm
RG002-1514	Relax Gelcell Cushion with Spacer Cover	15x14in
RG002-1616	Relax Gelcell Cushion with Spacer Cover	16x16in
RG002-1717	Relax Gelcell Cushion with Spacer Cover	17x17in
RG002-1816	Relax Gelcell Cushion with Spacer Cover	18x16in
RG002-1818	Relax Gelcell Cushion with Spacer Cover	18x18in
RG002-2018	Relax GelCell G2 Cushion With Spacer Cover	20x18in
RG003-1414	Relax GelCell G2 Cushion With Spacer Cover	14x14in
RG003-1515	Relax GelCell G2 Cushion With Spacer Cover	15x15in
RG003-1616	Relax GelCell G2 Cushion With Spacer Cover	16x16in
RG003-1618	Relax GelCell G2 Cushion With Spacer Cover	16x18in
RG003-1717	Relax GelCell G2 Cushion With Spacer Cover	17x17x1.5in
RG003-1816	Relax GelCell G2 Cushion With Spacer Cover	18x16x1.5in
RG003-1818	Relax GelCell G2 Cushion With Spacer Cover	18x18in
RG004-1514	Relax GelCell Cushion	15x14in
RG004-1616	Relax GelCell Cushion	16x16x2in
RG004-1717	Relax GelCell Cushion	17x17x2in
RG004-1816	Relax GelCell Cushion	18x16x2in
RG004-1818	Relax GelCell Cushion	18x18x2in
RG004-2018	Relax GelCell Cushion	20x18in
RG005-1414	Relax GelCell Cushion	14x14in
RG005-1515	Relax GelCell Cushion	15x15in
RG005-1616	Relax GelCell Cushion	16x16in
RG005-1618	Relax GelCell G2 Cushion	16x18in
RG005-1717	Relax GelCell G2 Cushion	17x17x1.5in



RG005-1816	Relax GelCell G2 Cushion	18x16x1.5in
RG005-1818	Relax GelCell G2 Cushion	18x18in
RT001-1416	Relax Trio Cushion	14x16in
RT001-1616	Relax Trio Cushion	16x16x1.5in
RT001-1717	Relax Trio Cushion	17x17x1.5in
RT001-1816	Relax Trio Cushion	18x16x1.5in
RT001-1818	Relax Trio Cushion	18x18x1.5in

## Annex II: Harmonised and other Standards

Applied Standards	Description of Standard
MDR 2017/754	Regulation (EU) 2017/745 of the European Parliament and of the Council, of 5 April 2017, on medical devices
ISO 13485:2016	Medical devices -- Quality management systems -- Requirements for regulatory purposes
ISO 14971:2019	Medical devices. Application of risk management to medical devices
ISO 15223-1 (2016)	Medical Devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General Requirements
ISO 15223-2 (2010)	Medical Devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 2: Symbol development, selection and validation.
ISO 10993-10: (2010)	ISO 10993-10:2010 describes the procedure for the assessment of medical devices and their constituent materials with regard to their potential to produce irritation and skin sensitization.
ISO 10993-1: (2018)	The general principles governing the biological evaluation of medical devices within a risk management process;
ISO 1041:2008 A1:2013	Harmonised standard. Information Supplied by the Manufacturer of Medical Devices
BS EN ISO 12952: Parts 1 & 2: (2010) BS 7175 (1989) BS 5852 Part 2: (1982)	Smouldering cigarette / Match flame equivalent Methods of test for the ignitability of bedcovers and pillows by smouldering and flaming ignition sources. Fire tests for furniture – Part 2. Methods of test for the ignitability of upholstered composites for seating by flaming sources.