Declaration of Conformity

Name & Address of the Manufacturer: Trulife,
39 East Davis Street
Trenton,
ON
Canada K8V 4K8

Single Registration Number: IE-AR-000004119

Authorised Rep: Trulife
Airton Road
Tallaght
Dublin 24
Ireland

Name of Device(s): Post Mastectomy Bra

Reference Codes:

210	BARBARA	4013	ALEXANDRA
190	IRENE	4019	JESSICA
330	SOPHIA	4030	EMILY
420	KATE	4040	HARPER
4002	LILY	4050	KENDRA
4012	TAYLOR		

Basic UDI-DI: 00645517BrasQ2

Intended Use: A post mastectomy bra is designed to hold in place external breast forms following mastectomy or lumpectomy surgery.

Classification: Class I

Rule: Rule 1 Annex VII – 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 I attached).

Approved by: Marion Donnelly **Date:** Nov. 17/23

Marion Donnelly
Operations Manager
(On behalf of Trulife)

Place of Issue: Trulife, Trenton, ON, Canada

Expiry Date: Nov. 17/24

Annex I: 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 1041:2008 A1:2013	Harmonised standard. Information Supplied by the Manufacturer of Medical Devices