Initiated by: R. Holmes 25/01/2023
Approved by: E. Redmond 25/01/2023
Released by: R. Holmes 25/01/2023

Declaration of Conformity

Name & Address of the Manufacturer: Trulife Limited,
Airton 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): Breast Care Products

Reference Code: See Annex I attached

Basic UDI-DI: 00643293Breastcare6Z

Ref: SQM67-1
Rev: 0

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Intended Use: Breastcare prostheses are designed to be used as a replacement of a natural breast.

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: _____ **Date:** 25/01/2023

Rebecca Holmes
Senior Quality Specialist
(On behalf of Trulife)

Place of Issue: Dublin, Ireland

Expiry Date: 25/01/2024

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Annex I

Item No./ Product Code	Size Range	Name
509	1-17	E Supreme
503	1-14 R&L	A Supreme
508	1-14	Symphony
641	1-14	Tropez
533	3-9	Triangular Partial
531	1-11	Partial
571	3-14	Bella
701	1-14	Duette Triangle
471	1-17	Silk Triangle
483	1-17	Silk Encore Triangle
472	1-17	Silk Triangle Plus
473	1-14	Silk Teardrop
475	1-14 R&L	Silk A Supreme
476	1-10	Silk Connect
478	1-14 R&L	Silk Xtend
477	1-14	Silk Flex
481	1-14	Silk Ultima Triangle
485	2-14	Silk Curve
616	1-14	Tri Featherweight
611	3-14	Tri Leisureform
615	1-14	Featherweight
495	1-14	BodiCool Wave Triangle
101	2-12	Impressions II
102	4-12	Impressions II Encore
151	3-14	Sublime Arís
822	S-XL	ReCover Shell
356	1-11	Teardrop Partial Encore
497	2-10 R&L	BodiCool Assymetrical
498	2-10 R&L	Assymetrical
535	3-9	Tri- Partial Encore
153	3-12	Cara
622	3-12 R&L	Luna
N001	1-17	Breastform Cover 101/ 471/ 472/ 476/ 481/ 495/ 571/ 701
D001	1-17	Breastform Cover 102/ 483
N002	3-14	Breastform Cover 151
N003	2-14	Breastform Cover 485/ 153
N004	1-14	Breastform Cover 508
N005	1-14	Breastform Cover 473/ 509
N006	1-14	Breastform Cover 477
N007	1-14 R&L	Breastform Cover 478/ 482
N008	1-14 R&L	Breastform Cover 475/ 503
N009	2-10 R&L	Breastform Cover 497/ 498

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Annex II: Harmonised and other Standards

Applied Standards	Description of Standard
MDR 2017/745	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 (2021)	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: (2021)	ISO 10993-10 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;