Customer Information - BreastCare

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Appendices
Appendix (A) Declaration of Conformity
Appendix (B) ISO Certificate
Appendix (C) BreastCare IFU
Appendix (D) BreastCare Catalogue

Section 1 – Manufacturers Details

1.1 Declaration of Conformity

An EU Declaration of Conformity (DoC) is a mandatory document that declares, as a medical device manufacturer, we are in conformity with the regulations as set out in MDR 2017/745. Our EU Declaration of Conformity for our BreastCare products can be found in Appendix (A). This includes the company's information, the name of the devices and their codes, their Basic UDI, intended use, the classification and rule, a statement taking responsibility for the products, and a signature on behalf of Trulife

1.2 Quality Management System

Trulife has been assessed and deemed to comply with the requirements of EN ISO 13485:2016. A copy of this certificate can be found in Appendix (B) of this document.

1.3 Information supplied by the Manufacturer – Labelling and Packaging

Examples of our standard product labelling and packaging can be seen in the images below. Our Instructions for Use (IFU's) can be found in Appendix (C). The IFU contains the basic operational "how to" information as well as any cautions and other general or device specific information. The IFU includes the regulatory steps that must be taken should any serious adverse incident take place with the product, or should patient safety be compromised.

All labels and packaging are compliant to EN ISO 15233-1 Medical Devices Symbols and the EU MDR 2017/745.

Any changes to labelling or packing are carried out as per our internal document control procedures. This ensures that the labels and packaging received by the customer have been reviewed and approved for use.

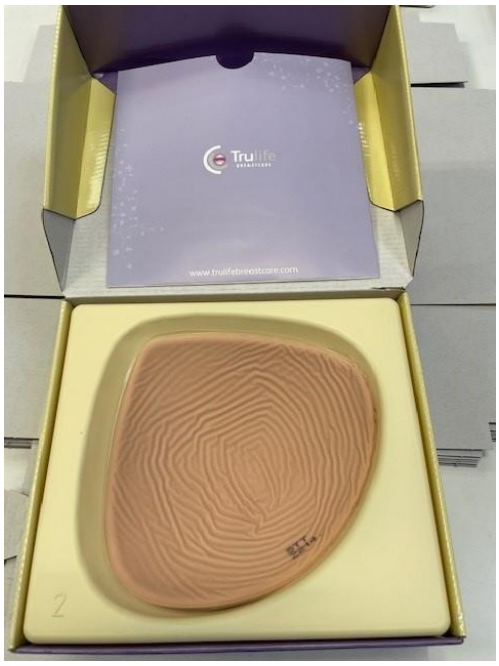

Image of Inner Packaging of BreastCare products

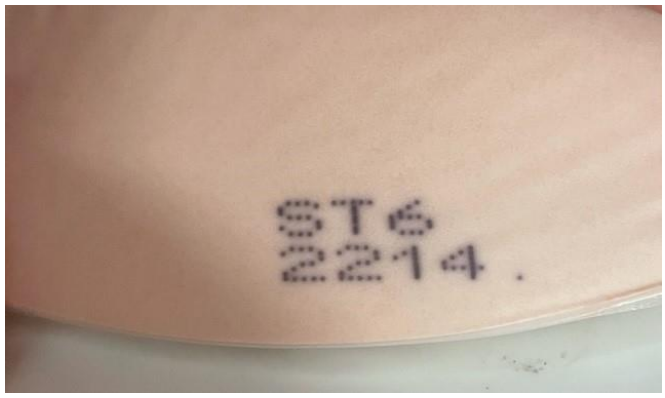

Image of Transfer on BreastCare products

Image of Outer Labels on BreastCare products

1.4 Risk Management

Trulife's risk management process is performed in accordance with the methodology described in ISO 14971:2019. Trulife has the relevant product expertise and historical experience to assign the appropriate risks to the products and risks identified during risk management determine internal and external testing requirements. All risks are reduced as far as possible and have an acceptable benefit-risk level.

1.5 General Safety and Performance Requirements

Our products achieve the intended performance and are designed and manufactured in such a way that, during normal conditions of use, they are suitable for their intended purpose.
The General Safety and Performance Requirements in accordance with Annex I of the European Medical Device Regulation 2017/745, for the BreastCare product range has been evaluated and is documented in our technical documentation.

Section 2 Product Design, Specification and Manufacture

2.1 Product Design

The Design History File retains all pertinent project data, (i.e. design verifications and validations, design transfer etc.) to demonstrate compliance with the design plan and all applicable regulations. The design control process ensures confidence that our products are safe, reliable, efficacious and meet all regulatory requirements prior to release for market. This is initiated for the following situations;

- The design and development of new products
- Changes to existing products following post market feedback
- Publication of the new or revised harmonised standards

2.2 Product Specification and Manufacture

Specification

For the complete range of Trulife BreastCare products and specifications, please refer to our catalogue in Appendix (D) and/or www.trulife.com

Manufacture

The BreastCare Product range are made up into three main families. The name of each family and an overview of the manufacturing steps to make these products are listed below.

P.U film and Silicone

- Sheets of polyurethane film are heat sealed to form the shape of the product of a particular size.
- The formed bag is then filled with silicone gel (Two- part addition cure gel).
- The neck of the bag is heat sealed.
- The product is moulded and cured for 4 hours.
- The product is inspected and trimmed.
- The product is then packed.

100% Silicone

- BP mould is filled with silicone to create a skin layer.
- After curing, mould is then filled with sugar bead and closed for filling.
- Mould is filled again with more silicone into the sugar beads.
- Once cured, product is demoulded, inspected and sent to be washed.
- The product is placed into an over to dry overnight.
- The product is then inspected, trimmed, and packed.

Foam

- Foam blocks are positioned onto a dye board that is the template for the BP size to be cut.
- Foam block and dye board are rolled through a cutting machine.
- Excess foam separates from the BP shape.
- Weighted BP's have silicone paste PU bag inserted into cut out at back of the BP.
- Plugs for the back of weight BPs are cut out of the same foam using a clicker tool.
- Glue is added to the back of the weighted PU bag and plug is pressed into place.
- The product is weighted, inspected, and trimmed.
- The product is then packed.
- Unweighted products, after cutting are inspected, trimmed and then packed.

All of Trulife products are non-sterile, latex free and do not contain phthalates. All raw materials used in BreastCare products comply with the requirements of the REACH Regulation and the RoHS Directive.

2.3 Routine Production

All inspection and test procedures carried out in the production area are in accordance with ISO 13485:2016. These procedures, work sheets etc. and the training associated with the proper performing of these tasks form part of the ISO 13485:2016 quality management system.

2.4 Traceability

All products are printed with a four-digit Lot number in YY/WW format. This ensures that all materials that were utilised in the manufacture of the product are traceable. Once packed, the Lot number and Date of Manufacture (DoM) are printed on the product packaging label and incorporated in a fourteen-digit G.T.I.N barcode. This allows for continued downstream traceability of our products throughout the supply chain.

2.5 Shelf Life and Product Life Cycle

Our BreastCare products are guaranteed for a period of two years from date of manufacture. Based on relevant durability testing, the product life cycle for BreastCare products is five years.

Section 3 Testing

3.1 Physical Testing (Internal)

BreastCare products are tested to verify all products meet their intended use. Our design inputs and product risk analysis dictate what testing is required. All testing carried out is documented.

Push Pull

The Push Pull test is used to determine the durability of a product and to stimulate the daily handling of a breast form being fitted in and removed from a bra pocket. BreastCare products are repeatedly compressed and pulled to demonstrate the placing and removing of the product from a bra.

Temperature Storage

The temperature that a product can be stored in is very important for product durability. Our products are tested in both freezer (-20°C) and oven temperatures (200°C) to ensure no permanent changes to the products occurs.

Panel Fitting

This test is used to evaluate the overall product characteristics with a target market group. Panel fitting us performed to gain feedback on the products performance and fit. The patient is given the breast corm to wear as they would their own breast form for a period of time. The feedback is reviewed towards product safety and performance validation.

Altitude

To determine if our silicone breast forms can withstand high altitudes, our altitude tests are conducted. Air travel is a popular mode of product transport that can have an effect on the products material behaviour at high altitudes.

Cleaning Test

Ease of cleaning is an important feature of Trulife products. The disinfectant cleaner market is very diverse with a wide range of cleaning solutions and suppliers. Therefore, we test the main chemistries found in a selection of cleaners. When testing a range of chemistries, we assess their effort on the products physical composition to ensure no damage occurs to the product. A list of recommended tested chemistries is available. Trulife products are recommended to be cleaner with a damp cloth of diluted cleaning solution and should not be submerged into any liquids, as this may affect the long-term durability of the products.

3.2 Biocompatibility Testing (External)

Irritation / Cytotoxicity Tests

Only in certain circumstances are we prepared to perform cytotoxicity and/or skin irritation tests for ISO 10993. Typically, these tests are not performed for low risk, non-invasive medical devices. Third party test facilities used by Trulife to carry out this external testing are ISO/IEC 17025 approved.

3.3 Clinical Evaluation Procedure

Trulife perform clinical evaluations to demonstrate the safety and effectiveness of our product throughout the collection, analysis and assessment of clinical data relating to the BreastCare product range. (Annex I MDR 2017/745)

This procedure is carried out during the validation phase of the design and development process prior to launching the medical device on the market.

Only products that are clinically evaluated and approved are launched onto the market.

3.4 Post Market Surveillance

The purpose of Post Market Surveillance (PMS) is to identify previously unrecognised adverse effects, as well as positive effects and to ensure that our products continue to be safe and effective on the market. Our PMS system consists of three main areas;

1. Customer Complaints, Trend Reports and Reportable Incidents
2. Direct feedback from customers
3. Review of published information

As per EU MDR 2017/745 Articles 83-86, Trulife's PMS procedure documents all post market surveillance activities.

3.5 Complaints Handling

Our complaints procedure complies with the requirements for handling complaints and processing incidents that are reportable to a regulatory body. The Quality Department performs regular trend analysis of reported incidents to provide useful information about the company's products and for the potential initiation of corrective / preventative actions.

Our customers complete an SQM4 Complaints Description Worksheet, stating if a patients safety was at risk, and email it to Quality_Department@trulife.com