EU DECLARATION OF CONFORMITY – REGULATION 2017/745

Number 004

Manufacturer:	OxMed International GmbH Groendahlscher Weg 87 46446 Emmerich am Rhein Germany
Eudamed SRN:	DE-MF-000004970
Product:	**ZenSiv 1-piece Colostomy pouches** See Schedule of Products on page 2 for codes.
Basic UDI-DI	426033315C1-FV2
Intended Purpose:	Ostomy pouches are used to collect waste from the body and are usually attached to the skin over a surgically made stoma.
Risk Class	Class I as per MDR 2017/745 Annex VIII Chapter III – Rule 1.
Statements:	The products are not sterile, do not have a measuring function and are not reusable surgical instruments.

OxMed International GmbH declares, under our sole responsibility, that the devices listed on the attached Device Schedule conform to the relevant provisions of Regulation (EU) 2017/745 of the European Parliament and of the Council dated 5th April 2017 on medical devices, and all relevant amendments, and are in accordance with Annex IX, Chapter I excluding 3, Annex II and Annex III.

Relevant Standards:

Standard	Description
EN ISO 14971:2019	Medical Devices – Application of Risk Management to Medical Devices
EN ISO 15223-1:2021	Medical Devices. Symbols to be used with information to be supplied by the manufacturer – General requirements
ISO 20417:2021	Medical devices - Information supplied by the manufacturer

Place and Date of Issue: Emmerich am Rhein, Germany. 3th October 2022

Signed:

J.C.H. van Kerkhof, Managing Director, OxMed International GmbH

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Oct 2022

SCHEDULE OF PRODUCTS

Packs for Sales

Product Code	Product Description
C1NB10	ZenSiv 1-p colostomy beige window filter Ø cut-to fit
C1NB10-HC	ZenSiv 1-p colostomy ultra-light beige window filter Ø cut-to fit
C1NB10-30	ZenSiv 1-p colostomy beige window filter Ø cut-to fit
C1NZ10-30	ZenSiv 1-p colostomy black window filter Ø cut-to fit
C1NB10V	ZenSiv 1-p colostomy beige window vent filter Ø cut-to fit
C1NZ10V	ZenSiv 1-p colostomy black window vent filter Ø cut-to fit
C1NB10V-HC-30	ZenSiv 1-p colostomy ultra-light beige window vent filter Ø cut-to fit
C1NZ10V-HC-30	ZenSiv 1-p colostomy ultra-light black window vent filter Ø cut-to fit
C1NB25	ZenSiv 1-p colostomy beige window filter pre-cut Ø 25mm
C1NB25V	ZenSiv 1-p colostomy beige window vent filter pre-cut Ø 25mm
C1NZ25V	ZenSiv 1-p colostomy black window vent filter pre-cut Ø 25mm
C1NB29	ZenSiv 1-p colostomy beige window filter pre-cut Ø 29mm
C1NB29V	ZenSiv 1-p colostomy beige window vent filter pre-cut Ø 29mm
C1NZ29V	ZenSiv 1-p colostomy black window vent filter pre-cut Ø 29mm
C1NB32	ZenSiv 1-p colostomy beige window filter pre-cut Ø 32mm
C1NB32V	ZenSiv 1-p colostomy beige window vent filter pre-cut Ø 32mm
C1NZ32V	ZenSiv 1-p colostomy black window vent filter pre-cut Ø 32mm
C1NB38	ZenSiv 1-p colostomy beige window filter pre-cut Ø 38mm
C1NB38V	ZenSiv 1-p colostomy beige window vent filter pre-cut Ø 38mm
C1NZ38V	ZenSiv 1-p colostomy black window vent filter pre-cut Ø 38mm
C1NC10	ZenSiv 1-p colostomy transparent window filter Ø cut-to fit
C1PB10	ZenSiv 1-p colostomy beige plaster window filter Ø cut-to fit
C1PB10-30	ZenSiv 1-p colostomy beige plaster window filter Ø cut-to fit
C1PZ10-30	ZenSiv 1-p colostomy black plaster window filter Ø cut-to fit
C1PB10V-30	ZenSiv 1-p colostomy beige plaster window vent filter Ø cut-to fit
C1PZ10V-30	ZenSiv 1-p colostomy black plaster window vent filter Ø cut-to fit
N1NB10	ZenSiv 1-p colostomy mini beige window filter Ø cut-to fit

Packs for Samples

Product Code	Product Description
C1NB10-6	ZenSiv 1-p colostomy beige window filter Ø cut-to fit
C1NZ10-6	ZenSiv 1-p colostomy black window filter Ø cut-to fit
C1NB10V-6	ZenSiv 1-p colostomy beige window vent filter Ø cut-to fit
C1NZ10V-6	ZenSiv 1-p colostomy black window vent filter Ø cut-to fit
C1NB10V-HC-6	ZenSiv 1-p colostomy ultra-light beige window vent filter Ø cut-to fit
C1NZ10V-HC-6	ZenSiv 1-p colostomy ultra-light black window vent filter Ø cut-to fit
C1PB10-6	ZenSiv 1-p colostomy beige plaster window filter Ø cut-to fit
C1PZ10-6	ZenSiv 1-p colostomy black plaster window filter Ø cut-to fit
C1PB10V-6	ZenSiv 1-p colostomy beige plaster window vent filter Ø cut-to fit
C1PZ10V-6	ZenSiv 1-p colostomy black plaster window vent filter Ø cut-to fit
N1NB10-6	ZenSiv 1-p colostomy mini beige window filter Ø cut-to fit
C1NZ25V-6	ZenSiv 1-p colostomy black window vent filter pre-cut Ø 25mm
C1NZ29V-6	ZenSiv 1-p colostomy black window vent filter pre-cut Ø 29mm
C1NZ32V-6	ZenSiv 1-p colostomy black window vent filter pre-cut Ø 32mm
C1NZ38V-6	ZenSiv 1-p colostomy black window vent filter pre-cut Ø 38mm