

EU DECLARATION OF CONFORMITY – REGULATION 2017/745

Number 007

Manufacturer: OxMed International GmbH
Groendahlscher Weg 87
46446 Emmerich am Rhein
Germany

Eudamed SRN: DE-MF-000004970

Product: **ZenSiv 1-piece Ileostomy pouches**
See Schedule of Products on page 2 for codes.

Basic UDI-DI 426033315D1-FV9

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. 04th October 2022

Signed:



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

SCHEDULE OF PRODUCTS

Packs for Sales

Product Code	Product Description
D1FB10XV	ZenSiv 1-p ileostomy flat hydrocolloid foam wafer beige window filter velcro closure vent Ø cut-to fit
D1FZ10XV	ZenSiv 1-p ileostomy flat hydrocolloid foam wafer black window filter velcro closure vent Ø cut-to fit
D1NB10	ZenSiv 1-p ileostomy beige window filter Ø cut-to fit
D1NZ10	ZenSiv 1-p ileostomy black window filter Ø cut-to fit
D1NB10-HC	ZenSiv 1-p ileostomy ultra-light beige window filter Ø cut-to fit
D1NB10X	ZenSiv 1-p ileostomy beige window filter velcro closure Ø cut-to fit
D1NZ10X	ZenSiv 1-p ileostomy black window filter velcro closure Ø cut-to fit
D1NB10X-HC	ZenSiv 1-p ileostomy ultra-light beige window filter velcro closure Ø cut-to fit
D1NB10XV	ZenSiv 1-p ileostomy beige window filter velcro closure vent Ø cut-to fit
D1NZ10XV	ZenSiv 1-p ileostomy black window filter velcro closure vent Ø cut-to fit
D1NB10XV-HC	ZenSiv 1-p ileostomy ultra-light beige window filter velcro closure vent Ø cut-to fit
D1NB25	ZenSiv 1-p ileostomy beige window filter pre-cut Ø 25mm
D1NB25X	ZenSiv 1-p ileostomy beige window filter velcro closure pre-cut Ø 25mm
D1NB25XV	ZenSiv 1-p ileostomy beige window filter velcro closure vent pre-cut Ø 25mm
D1NZ25XV	ZenSiv 1-p ileostomy black window filter velcro closure vent pre-cut Ø 25mm
D1NB29X	ZenSiv 1-p ileostomy beige window filter velcro closure pre-cut Ø 29mm
D1NB29XV	ZenSiv 1-p ileostomy beige window filter velcro closure vent pre-cut Ø 29mm
D1NZ29XV	ZenSiv 1-p ileostomy black window filter velcro closure vent pre-cut Ø 29mm
D1NB32	ZenSiv 1-p ileostomy beige window filter pre-cut Ø 32mm
D1NB32X	ZenSiv 1-p ileostomy beige window filter velcro closure pre-cut Ø 32mm
D1NB32XV	ZenSiv 1-p ileostomy beige window filter velcro closure vent pre-cut Ø 32mm
D1NZ32XV	ZenSiv 1-p ileostomy black window filter velcro closure vent pre-cut Ø 32mm
D1NB38	ZenSiv 1-p ileostomy beige window filter pre-cut Ø 38mm
D1NB38X	ZenSiv 1-p ileostomy beige window filter velcro closure pre-cut Ø 38mm
D1NB38XV	ZenSiv 1-p ileostomy beige window filter velcro closure vent pre-cut Ø 38mm
D1NZ38XV	ZenSiv 1-p ileostomy black window filter velcro closure vent pre-cut Ø 38mm
D1ND10	ZenSiv 1-p ileostomy beige window Ø cut-to fit
D1ND10-HC	ZenSiv 1-p ileostomy ultra-light beige window Ø cut-to fit
D1NT10	ZenSiv 1-p ileostomy clear no filter Ø cut-to fit
D1NT10XV	ZenSiv 1-p ileostomy transparent window filter velcro closure vent Ø cut-to fit
D1NT44	ZenSiv 1-p ileostomy transparent filter pre-cut Ø 44mm
D1NT51	ZenSiv 1-p ileostomy transparent filter pre-cut Ø 51mm
M1NB10	ZenSiv 1-p ileostomy mini beige window filter Ø cut-to fit
M1NB10X	ZenSiv 1-p ileostomy mini beige window filter velcro closure Ø cut-to fit

Packs for Samples

Product Code	Product Description
D1FB10XV-5	ZenSiv 1-p ileostomy flat hydrocolloid foam wafer beige window filter velcro closure vent Ø cut-to fit
D1FZ10XV-5	ZenSiv 1-p ileostomy flat hydrocolloid foam wafer black window filter velcro closure vent Ø cut-to fit
D1NB10X-5	ZenSiv 1-p ileostomy beige window filter velcro closure Ø cut-to fit
D1NZ10X-5	ZenSiv 1-p ileostomy black window filter velcro closure Ø cut-to fit
D1NB10XV-5	ZenSiv 1-p ileostomy beige window filter velcro closure vent Ø cut-to fit
D1NZ10XV-5	ZenSiv 1-p ileostomy black window filter velcro closure vent Ø cut-to fit
M1NB10X-5	ZenSiv 1-p ileostomy mini beige window filter velcro closure Ø cut-to fit
D1NZ10-5	ZenSiv 1-p ileostomy black window filter Ø cut-to fit
D1NZ25XV-5	ZenSiv 1-p ileostomy black window filter velcro closure vent pre-cut Ø 25mm
D1NZ29XV-5	ZenSiv 1-p ileostomy black window filter velcro closure vent pre-cut Ø 29mm
D1NZ32XV-5	ZenSiv 1-p ileostomy black window filter velcro closure vent pre-cut Ø 32mm
D1NZ38XV-5	ZenSiv 1-p ileostomy black window filter velcro closure vent pre-cut Ø 38mm