

EU DECLARATION OF CONFORMITY – REGULATION 2017/745

Number 002

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

Eudamed SRN: DE-MF-000004970

Product: **ZenSiv Baseplates cut-to fit**
See Schedule of Products on page 2 for codes.

Basic UDI-DI 426033315B2-CTFHD

Intended Purpose: Ostomy pouches are used to collect waste from the body and are usually attached to the skin over a surgically made stoma. All 1-piece pouches and 2-piece flanges feature a skin friendly hydrocolloid wafer for adhesion to the body and this is protected before use with a release film that shows a cutting guide.

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. 13th June 2022

Signed:



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

SCHEDULE OF PRODUCTS

Packs for Sales

Product Code	Product Description
B2C510	ZenSiv 2-p Convex normal baseplate 50 ring Ø cut-to fit
B2C610	ZenSiv 2-p Convex normal baseplate 60 ring Ø cut-to fit
B2C710	ZenSiv 2-p Convex normal baseplate 70 ring Ø cut to fit
B2CP510	ZenSiv 2-p Convex Plaster baseplate 50 ring Ø cut-to fit
B2CP610	ZenSiv 2-p Convex Plaster baseplate 60 ring Ø cut-to fit
B2CP710	ZenSiv 2-p Convex Plaster baseplate 70 ring Ø cut-to fit
B2N410	ZenSiv 2-p normal baseplate 40 ring Ø cut-to fit
B2N410-HC	ZenSiv 2-p baseplate ultra-light 40 ring Ø cut-to fit
B2N510	ZenSiv 2-p normal baseplate 50 ring Ø cut-to fit
B2N510-HC	ZenSiv 2-p baseplate ultra-light 50 ring Ø cut-to fit
B2N610	ZenSiv 2-p normal baseplate 60 ring Ø cut-to fit
B2N610-HC	ZenSiv 2-p baseplate ultra-light 60 ring Ø cut-to fit
B2N710	ZenSiv 2-p normal baseplate 70 ring Ø cut-to fit
B2N710-HC	ZenSiv 2-p baseplate ultra-light 70 ring Ø cut-to fit
B2N810	ZenSiv 2-p normal baseplate 80 ring Ø cut-to fit
B2N1000	ZenSiv 2-p normal baseplate 105 ring Ø cut-to fit
B2P410	ZenSiv 2-p plaster baseplate 40 ring Ø cut-to fit
B2P510	ZenSiv 2-p plaster baseplate 50 ring Ø cut-to fit
B2P610	ZenSiv 2-p plaster baseplate 60 ring Ø cut-to fit
B2P710	ZenSiv 2-p plaster baseplate 70 ring Ø cut-to fit

Packs for Samples

Product Code	Product Description
B2C510-2	ZenSiv 2-p Convex normal baseplate 50 ring Ø cut-to fit
B2C610-2	ZenSiv 2-p Convex normal baseplate 60 ring Ø cut-to fit
B2N410-2	ZenSiv 2-p normal baseplate 40 ring Ø cut-to fit
B2N510-2	ZenSiv 2-p normal baseplate 50 ring Ø cut-to fit
B2N610-2	ZenSiv 2-p normal baseplate 60 ring Ø cut-to fit
B2N710-2	ZenSiv 2-p normal baseplate 70 ring Ø cut-to fit
B2P410-2	ZenSiv 2-p plaster baseplate 40 ring Ø cut-to fit
B2P510-2	ZenSiv 2-p plaster baseplate 50 ring Ø cut-to fit
B2P610-2	ZenSiv 2-p plaster baseplate 60 ring Ø cut-to fit
B2P710-2	ZenSiv 2-p plaster baseplate 70 ring Ø cut-to fit