DECLARATION OF CONFORMITY

Document Number   **001**

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

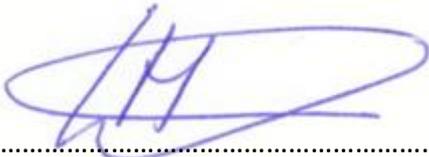**Codes:**   See attached schedule

Classification: Class 1
                      (Classified as per Annex IX of EC Council Directive 93/42/EEC, Section III
                      Rule 1 applies)

Declaration: OxMed International GmbH declare that the devices listed in the schedule are
                      designated as Class I and conform to the relevant provisions of the EC Council
                      Directive 93/42/EEC, dated 14th June 1993, and all relevant amendments and are in
                      accordance with Annex VII, as implemented by the European Union's Medical
                      Devices Regulations

                      The products are neither sterile nor have a measuring function.

                      We believe our Vigilance System complies with the requirements of the European
                      Medical Devices Vigilance System Guidelines.

Signed..
          Heleen de Weert, Managing Director, OxMed International GmbH

          Date 26-05-2020

SCHEDULE OF PRODUCTS

A2001	ZenSetiv hydrocolloid paste 57 gram tube
A2010	ZenSetiv hydrocolloid mouldable rings 50mm
A2011	ZenSetiv hydrocolloid mouldable rings 50mm/4mm thick
A2013	ZenSetiv hydrocolloid mouldable rings 100mm
A2015	ZenSetiv hydrocolloid half moon strips
A2016	ZenSetiv microporous half moon strips
A2018	ZenSetiv protective powder 28,3 gram
A2020	ZenSetiv absorbent sachets
ABS125	ZenSetiv Stoma Belt 125/2,8
ASP2100	ZenSetiv Silicon Plaster 10x10
ASP275	ZenSetiv Silicon Plaster 7,5x7,5
ASPLA100	ZenSetiv Stoma Plaster 10x10 cm
ASPLA75	ZenSetiv Stoma Plaster 7,5 x 7,5 cm
ASR2100	ZenSetiv Silicon Plaster with split 10x10
ASR275	ZenSetiv Silicon Plaster with split 7,5x7,5
AST25150	ZenSetiv Silicon Tape 2,5 cm x 1,5 m
HSR125	Hydrocolloid Shape Regular Square with rounded edges (12,5 x 12,5 cm)
HSR200	Hydrocolloid Shape Regular Square with rounded edges (20 x 20 cm)
HSR090	Hydrocolloid Shape Regular Round (9 Ø cm)
HSR120	Hydrocolloid Shape Regular Round (12 Ø cm)
HSR522	Hydrocolloid Shape Regular Strips with rounded edges (5 x 22 cm)
HSU200	Hydrocolloid Shape Ultra Thin Square with rounded edges (20 x 20 cm)
HSU311	Hydrocolloid Shape Ultra Thin Strips with rounded edges (3 x 11 cm)
HSU511	Hydrocolloid Shape Ultra Thin Strips with rounded edges (5 x 11 cm)
HSF311	Hydrocolloid Shape Soft Foam Strips with rounded edges (3 x 11 cm)
HSF511	Hydrocolloid Shape Soft Foam Strips with rounded edges (5 x 11 cm)
HSF522	Hydrocolloid Shape Soft Foam Strips with rounded edges (5 x 22 cm)
B2C510	ZenSiv 2-p Convex normal baseplate 50 ring Ø cut-to fit
B2C525	ZenSiv 2-p Convex normal baseplate 50 ring pre-cut Ø 25mm
B2C532	ZenSiv 2-p Convex normal baseplate 50 ring pre-cut Ø 32mm
B2C610	ZenSiv 2-p Convex normal baseplate 60 ring Ø cut-to fit
B2C622	ZenSiv 2-p Convex normal baseplate 60 ring pre-cut Ø 22mm
B2C625	ZenSiv 2-p Convex normal baseplate 60 ring pre-cut Ø 25mm
B2C628	ZenSiv 2-p Convex normal baseplate 60 ring pre-cut Ø 28mm
B2C632	ZenSiv 2-p Convex normal baseplate 60 ring pre-cut Ø 32mm
B2C635	ZenSiv 2-p Convex normal baseplate 60 ring pre-cut Ø 35mm
B2C638	ZenSiv 2-p Convex normal baseplate 60 ring pre-cut Ø 38mm

B2C641	ZenSiv 2-p Convex normal baseplate 60 ring pre-cut Ø 41mm
B2C645	ZenSiv 2-p Convex normal baseplate 60 ring pre-cut Ø 45mm
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
B2CP525	ZenSiv 2-p Convex Plaster baseplate 50 ring pre-cut Ø 25mm
B2CP532	ZenSiv 2-p Convex Plaster baseplate 50 ring pre-cut Ø 32mm
B2CP610	ZenSiv 2-p Convex Plaster baseplate 60 ring Ø cut-to fit
B2CP632	ZenSiv 2-p Convex Plaster baseplate 60 ring pre-cut Ø 32mm
B2CP638	ZenSiv 2-p Convex Plaster baseplate 60 ring pre-cut Ø 38mm
B2CP710	ZenSiv 2-p Convex Plaster baseplate 70 ring Ø cut to fit
B2N1000	ZenSiv 2-p normal baseplate 105 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
B2N525	ZenSiv 2-p normal baseplate 50 ring pre-cut Ø 25mm
B2N529	ZenSiv 2-p normal baseplate 50 ring pre-cut Ø 29mm
B2N532	ZenSiv 2-p normal baseplate 50 ring pre-cut Ø 32mm
B2N538	ZenSiv 2-p normal baseplate 50 ring pre-cut Ø 38mm
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
B2N625	ZenSiv 2-p normal baseplate 60 ring pre-cut Ø 25mm
B2N629	ZenSiv 2-p normal baseplate 60 ring pre-cut Ø 29mm
B2N632	ZenSiv 2-p normal baseplate 60 ring pre-cut Ø 32mm
B2N638	ZenSiv 2-p normal baseplate 60 ring pre-cut Ø 38mm
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
B2P410	ZenSiv 2-p plaster baseplate 40 ring Ø cut-to fit
B2P510	ZenSiv 2-p plaster baseplate 50 ring Ø cut-to fit
B2P525	ZenSiv 2-p plaster baseplate 50 ring Ø pre-cut 25mm
B2P529	ZenSiv 2-p plaster baseplate 50 ring Ø pre-cut 29mm
B2P532	ZenSiv 2-p plaster baseplate 50 ring Ø pre-cut 32mm
B2P538	ZenSiv 2-p plaster baseplate 50 ring Ø pre-cut 38mm
B2P610	ZenSiv 2-p plaster baseplate 60 ring Ø cut-to fit
B2P625	ZenSiv 2-p plaster baseplate 60 ring Ø pre-cut 25mm
B2P629	ZenSiv 2-p plaster baseplate 60 ring Ø pre-cut 29mm
B2P632	ZenSiv 2-p plaster baseplate 60 ring Ø pre-cut 32mm
B2P638	ZenSiv 2-p plaster baseplate 60 ring Ø pre-cut 38mm
B2P710	ZenSiv 2-p plaster baseplate 70 ring Ø cut-to fit
C1CLB10V	ZenSiv 1-p colostomy convex large beige window vent filter Ø cut to fit
C1CMB10V	ZenSiv 1-p colostomy convex medium beige window vent filter Ø cut to fit
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
C1NB10V	ZenSiv 1-p colostomy beige window vent filter Ø cut-to fit
C1NB10V-HC-30	ZenSiv 1-p colostomy ultra-light beige 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
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
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
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
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
C1PB10V-30	ZenSiv 1-p colostomy beige plaster window vent filter Ø cut-to fit
C2B4	ZenSiv 2-p colostomy beige window filter 40 ring
C2B5	ZenSiv 2-p colostomy beige window filter 50 ring
C2B5V	ZenSiv 2-p colostomy beige window vent filter 50 ring
C2B6	ZenSiv 2-p colostomy beige window filter 60 ring
C2B6V	ZenSiv 2-p colostomy beige window vent filter 60 ring
C2B7	ZenSiv 2-p colostomy beige window filter 70 ring
C2B8	ZenSiv 2-p colostomy beige window filter 80 ring
C2C6	ZenSiv 2-p colostomy clear filter 60 ring
D1CLB10XV	ZenSiv 1-p ileostomy convex large beige window filter vent velcro, closure Ø 10-45
D1CMB10XV	ZenSiv 1-p ileostomy convex medium beige window filter vent velcro, closure Ø 10-38
D1NB10	ZenSiv 1-p ileostomy beige 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
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
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-cutØ 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-cutØ 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
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
D1ND10	ZenSiv 1-p ileostomy beige window Ø cut-to fit
D1NT10	ZenSiv 1-p ileostomy clear no filter Ø cut-to fit
D1NT29	ZenSiv 1-p ileostomy transparent filter pre-cut Ø 29mm
D1NT29X	ZenSiv 1-p ileostomy transparent filter velcro closure pre-cut Ø 29mm
D1NT44	ZenSiv 1-p ileostomy transparent filter pre-cut Ø 44mm
D1NT44X	ZenSiv 1-p ileostomy transparent filter velcro closure pre-cut Ø 44mm
D1NT51	ZenSiv 1-p ileostomy transparent filter pre-cut Ø 51mm
D1NT51X	ZenSiv 1-p ileostomy transparent filter velcro closure pre-cut Ø 51mm
D2B4	ZenSiv 2-p ileostomy beige window filter 40 ring
D2B5	ZenSiv 2-p ileostomy beige window filter 50 ring
D2B5X	ZenSiv 2-p ileostomy beige window filter velcro closure 50 ring
D2B5XV	ZenSiv 2-p ileostomy beige window filter velcro closure vent 50 ring
D2B6	ZenSiv 2-p ileostomy beige window filter 60 ring
D2B6X	ZenSiv 2-p ileostomy beige window filter velcro closure 60 ring
D2B6V	ZenSiv 2-p ileostomy beige window filter vent 60 ring
D2B6XV	ZenSiv 2-p ileostomy beige window filter velcro closure vent 60 ring
D2B7	ZenSiv 2-p ileostomy beige window filter 70 ring
D2B7V	ZenSiv 2-p ileostomy beige window filter vent 70 ring
D2B7X	ZenSiv 2-p ileostomy beige window filter velcro closure 70 ring
D2B7XV	ZenSiv 2-p ileostomy beige window filter velcro closure vent 70 ring
D2B8	ZenSiv 2-p ileostomy beige window filter 80 ring
D2B10	ZenSiv 2-p ileostomy beige window filter 105 ring
D2T10	ZenSiv 2-p ileostomy transparent 105 ring
D2T6	ZenSiv 2-p ileostomy transparent 60 ring
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
M2B5	ZenSiv 2-p ileostomy mini beige window filter 50 ring
N1NB10	ZenSiv 1-p colostomy mini beige window filter Ø cut-to fit
N2B5	ZenSiv 2-p colostomy mini beige window filter 50 ring
U1CMB10F	ZenSiv 1-p urostomy convex medium beige window flex tap Ø cut to fit
U1NB10F	ZenSiv 1-p urostomy beige window flex tap Ø cut-to fit
U1NB10F-HC	ZenSiv 1-p urostomy ultra-light beige window flex tap Ø cut-to fit
U1NB25F	ZenSiv 1-p urostomy beige window flex tap pre-cut Ø 25mm
U1NB32F	ZenSiv 1-p urostomy beige window flex tap pre-cut Ø 32mm
U1NB38F	ZenSiv 1-p urostomy beige window flex tap pre-cut Ø 38mm
U1NC10F	ZenSiv 1-p urostomy transparent flex tap Ø cut-to fit
U1PB10F	ZenSiv 1-p urostomy beige plaster window flex tap Ø cut-to fit
U2B4F	ZenSiv 2-p urostomy beige window flex tap 40 ring
U2B5F	ZenSiv 2-p urostomy beige window flex tap 50 ring
U2C5F	ZenSiv 2-p urostomy transparent flex tap 50 ring
U2B6F	ZenSiv 2-p urostomy beige window flex tap 60 ring

U2C6F	ZenSiv 2-p urostomy transparent flex tap 60 ring
U2B7F	ZenSiv 2-p urostomy beige window flex tap 70 ring
P1NT10	ZenSiv 1-p (ileostomy or colostomy) Post-Op pouch, beige non-woven, transparent access panel, velcro closure, tap, cut to fit 10-100 mm
ZSA2011	ZenSetiv adhesive Remover Spray 50ml (silicone based)