

1. Company data

1.1. Manufacturer:

Name ConvaTec Limited
Address First Avenue
Deeside Industrial Park
Flintshire, CH5 2NU
Country UK
Website www.convatec.com

1.2. Dealer:

Name ConvaTec Denmark A/S
Address Skinderskovvej 32-36
2730 Herlev
Phone no. 48 16 70 00
Fax no. 44 41 19 93
E-mail convatec.danmark@convatec.com
Website www.convatec.dk

1.3. Distributor:

Name Biofarma Logistik A/S
Address Naverland 22
2600 Glostrup, Denmark
Phone no. 43 27 03 13
Fax no. 43 27 03 04
E-mail ordre@biofarma.dk
Website www.biofarma.dk

Quality management systems:

Manufacturer: ISO 13485

2. Product

2.1 Trade name Natura Stomahesive® Wafer
Natura Durahesive® Wafer

2.2. List of product range:

32 mm, 38 mm, 45 mm, 57mm, 70 mm, 100 mm

2.3. More information about the product

See homepage.

Natura Durahesive Convex Flexible Wafer: A flanged Convex Disc which is mounted to Trilaminat Durahesive Adhesive. A white square nonwoven collar is attached between the edges of the flange and the Disc. Natura Flexible Wafer with Border: A flanged Stomahesive adhesive disc with a white square non-woven collar.

3. Product components

(For sterile products including the item package/sterile barrier)

Cardboard: -

Paper: -

Glass: -

Metal: -

Latex: -

Cotton: -

Other: Yes

Organic: -

Hydrocolloid Powder
Rubber
Antioxidant
Tackifier Resin
Mineral Oil

3.2. Plastics:

Types of plastic: Polyethylene
Polyethylene Vinyl Acetate
Polyester
Polystyrene

PVC: NO

If PVC, state plasticiser: _____

% of PVC: _____

3.3. Heavy metals, chlorine, etc.:

Heavy metals: -

Types: _____

Chlorine bleached material:

Recycled materials:

Are substances from the Environmental Agency's list of undesirable substances included? :

State substances:

4. Packaging components

(For sterile products **excluding** the item package/sterile barrier)

Cardboard:

Paper:

Glass:

Metal:

Latex:

Cotton:

Other:

Organic:

4.2. Plastics:

Types of plastic: PVC
Low Density Polyethylene (LDPE)

PVC:

If PVC, state plasticiser: None

% of PVC: 90 % PVC

4.3. Heavy metals, chlorine, etc.:

Heavy metals:

Types:

Chlorine bleached material:

Recycled materials:

State any substances from the Environmental Agency's list of undesirable substances: None

5. CE marking

5.1. CE mark: No:

Yes:
(No NB no.)

Class:

6. Environmental information

6.1. Does a recognised env. label exist for the product area? Yes: No:

6.2. Does the product carry an environmental label? No: Yes: Label:

6.3. Environmental management systems: (State recognised environmental management systems, if any)

Manufacturer: None

Distributor: Not certified.

7. Shelf life

Shelf life after date of manufacture / date of sterilisation:

8. Recommended storage and handling

State recommendations Room temperature, Keep Dry, Avoid High Humidity

9. Recommendations for waste handling

Recommendation = X	Incineration	Landfill	Recycling	Recycling label
Product	X			
Item package	X			
Inner package	X			
Transport packaging			X	

Natura wafers

List of product range

Manufacturer product no.	Distributor product no.	EAN no. sales unit	Description	Size	Packaging unit	No. of packs per trsp carton	No. of cartons per pallet	Sterile
411800	411800	768455120963	Natura Durahesive Moldable, formbar med hydrokolloidklæber, Small	45mm	10	16		No
411802	411802	768455120970	Natura Durahesive Moldable, formbar med hydrokolloidklæber, Medium	45mm	10	16		No
411804	411804	768455120987	Natura Durahesive Moldable, formbar med hydrokolloidklæber, Large	57mm	10	16		No
411806	411806	768455120994	Natura Durahesive Moldable, formbar med hydrokolloidklæber, Extra Large	70mm	10	16		No
411801	411801	768455100453	Natura Stomahesive Moldable, formbar med hydrokolloidklæber, Small	45mm	10	10		No
411803	411803	768455100460	Natura Stomahesive Moldable, formbar med hydrokolloidklæber, Medium	45mm	10	10		No
411805	411805	768455100477	Natura Stomahesive Moldable, formbar med hydrokolloidklæber, Large	57mm	10	10		No
411807	411807	768455121007	Natura Stomahesive Moldable, formbar med hydrokolloidklæber, Extra Large	70mm	10	10		No
413154	413154	768455121151	Natura Durahesive 38 mm	38mm	10	10		No
413155	413155	768455121168	Natura Durahesive 45 mm	45mm	10	10		No
413156	413156	768455121175	Natura Durahesive 57 mm	57mm	10	10		No
413157	413157	768455121182	Natura Durahesive 70 mm	70mm	10	10		No
401574	401574	768455120666	Natura Stomahesive 38 mm	38mm	10	10		No
401575	401575	768455120673	Natura Stomahesive 45 mm	45mm	10	10		No
401576	401576	768455120680	Natura Stomahesive 57 mm	57mm	10	10		No
401577	401577	768455120697	Natura Stomahesive 70 mm	70mm	10	10		No
125263	125263	768455120475	Natura Stomahesive Flexible med akrylatklæber	38mm	10	10		No
125264	125264	768455120482	Natura Stomahesive Flexible med akrylatklæber	45mm	10	10		No
125265	125265	768455120499	Natura Stomahesive Flexible med akrylatklæber	57mm	10	10		No
125266	125266	768455120505	Natura Stomahesive Flexible med akrylatklæber	70mm	10	10		No
410294	410294	768455089697	Natura Stomahesive Flexible med hydrokolloidklæber	38mm	10	10		No
410295	410295	768455122615	Natura Stomahesive Flexible med hydrokolloidklæber	45mm	10	10		No
410296	410296	768455122622	Natura Stomahesive Flexible med hydrokolloidklæber	57mm	10	10		No
410297	410297	768455089727	Natura Stomahesive Flexible med hydrokolloidklæber	70mm	10	10		No
413177	413177	768455122639	Natura Durahesive convex med akrylatklæber 13 mm i 45mm koblingsring	45/13mm	10	20	18	No
413178	413178	768455122646	Natura Durahesive convex med akrylatklæber 16 mm i 45mm koblingsring	45/16mm	10	20	18	No
413179	413179	768455122653	Natura Durahesive convex med akrylatklæber 19 mm i 45mm koblingsring	45/19mm	10	20	18	No
413180	413180	768455122660	Natura Durahesive convex med akrylatklæber 22 mm i 45mm koblingsring	45/22mm	10	20	18	No
413181	413181	768455122677	Natura Durahesive convex med akrylatklæber 25 mm i 45mm koblingsring	45/25mm	10	20	18	No
413182	413182	768455122684	Natura Durahesive convex med akrylatklæber 28 mm i 45mm koblingsring	45/28mm	10	20	18	No
413183	413183	768455122691	Natura Durahesive convex med akrylatklæber 32 mm i 45mm koblingsring	45/32mm	10	20	18	No
413184	413184	768455122707	Natura Durahesive convex med akrylatklæber 35 mm i 45mm koblingsring	45/35mm	10	20	18	No
413185	413185	768455122714	Natura Durahesive convex med akrylatklæber 38 mm i 57mm koblingsring	57/38mm	10	20	18	No
413186	413186	768455122721	Natura Durahesive convex med akrylatklæber 41 mm i 57mm koblingsring	57/41mm	10	20	18	No
413187	413187	768455122738	Natura Durahesive convex med akrylatklæber 45 mm i 57mm koblingsring	57/45mm	10	20	18	No
413188	413188	768455122745	Natura Durahesive convex med akrylatklæber 50 mm i 57mm koblingsring	57/50mm	10	20	18	No
404592	404592	768455092666	Natura Durahesive Moldable convex, formbar med akrylatklæber, Small	45mm	10	12		No
404593	404593	768455092673	Natura Durahesive Moldable convex, formbar med akrylatklæber, Medium	45mm	10	12		No
404594	404594	768455092680	Natura Durahesive Moldable convex, formbar med akrylatklæber, Large	57mm	10	12		No