

andent

— choose andent ,choose quality



Andent Dental Co.,Ltd





Replaceable film face shield

- For protection against debris during oral prophylaxis and cavity preparation
- Film: 100% Optically ANTI-FOD PET
- Fits over glasses and face mask

Item	Description
F02	blue frame, 28x19CM

F02 Package A: Box of set / 10 films+1frame, 0box/Carton, CTN SIZE: 52x42x45cm

F02 Package B: Bag of set / 10 films+1 frame , 80bags/carton, CTN SIZE: 52x42x45cm

F02S Package C: Bag of set / 10 films , 100bags/carton, CTN SIZE: 37x33x21cm



Eyeglass Face shield

- Human body engineering glasses frame, wear comfortable and convenient
- Medical grade PET double anti-fog

Item	Description
F13B	blue frame
F13P	pink frame

F13 Package A: Box of set / 10 films+1frame,50box/Carton, CTN SIZE: 52x42x45cm

F13 Package B: Bag of set / 10 films+1 frame , 150bags/cartons, CTN SIZE: 52X42X45cm

F13S Package C: Bag of set / 10 films , 100bags/carton, CTN SIZE: 37x33x21cm

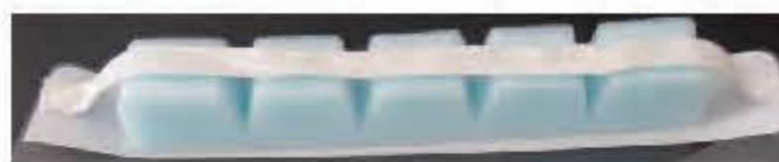


Disposable face shield

- Double anti-fog PET. Thickness:0.18mm~0.3mm
- Size:32x19CM 32x22CM 34x25CM
- OEM service.

Item	Description
F07A	Film 32*19CM
F07B	Film 32*22CM
F07C	Film 34*25CM

Package: Bag of 1; 200bag/Carton



Disposable Face Mask

- Anti-fog shields
- Comfortable,soft and non-irritating
- Water proof,execlent filtrataion (99.5% at 3microns)
- Permits air to pass through mask to prevent shield from fogging

Item	Description
F08B	blue
F08P	pink
F08U	purple
F08G	green

Package: Box of 50

Certificate

CERTIFICATE 认证证书

POSI CERTIFICATE

This is to certify that the Quality Management System of

Andent Dental Co., Ltd

Business License Number: 9113098356197719C
Registered Address: Zhaili Village, Qijiawu Town, Huanghua City, Hebei province, China
Audit Address: Zhaili Village, Qijiawu Town, Huanghua City, Hebei province, China

applicable to

Production and sales of: Disposable Dental Brush (Micro Applicator, Brush applicator, Brush tip, Brush Holder), Composite Syringe Gun, Medical Face Shield, Cheek retractor (Surgical dental retractor), Saliva ejector (Surgical aspirator, Oral Evacuation tips), Air water syringe tips, Disposable Mirror, Disposable Prob, Dental dispenser Gun, Dental Wedge, Medical eye shield, Orthodontic Invisible Braces/Chevies, Orthodontic Bracket (Orthodontic Accessory); Production and sales of: Composite Gun Bullets, Disposable Forceps, Endo Clean Sand, Endo Clean Sponges, Denture box, milk tooth box, Denture package box, Dental bib clip, Universal barrier film, Acrylic Orthodontic Wire box, Acrylic dental products box, Bur box, bur holder, Impression Tray, Impression tray base, HP mixing tips, intra-oral tip, Mixing bowl, Mixing well, Silicone Rubber cup, Mix Spatular, Mix rod, Curved Utility Syringe, Amalgam Carrier, Teeth separate film, X-ray Film Holder, Dental instrument Tray, Cotton roll dispenser, Instrument sterilize Container, Silicone instrument code ring, Prophy cup, Prophy brush (export only); Sales of Dental contristor, Photographic mirror: (export only), Cotton roll

has been assessed and registered by POSI against the provisions of
ISO13485:2016

This registration is subject to the company maintaining a quality management system, to the above standard, which will be monitored by POSI

Please consult the website: www.posicert.com

The certificate information is also available on the CNCA official website: <http://cx.cnca.cn>.



Jie Shan
General Manager

Certificate Registration No: POSIMD00012
Initial issue date: 2018.12.25 Issue date: 2021.12.23 Valid until: 2024.12.24

Shanghai POSI Certification Co., Ltd.

Room 1301-C-7, No. 500, Century Avenue, Pudong New Area, Shanghai, China. Email: info@posicert.com



CIBG
Ministerie van Volksgezondheid,
Welzijn en Sport

> Retouradres Postbus 16114 2500 RC Den Haag

Lotus NL B.V.
T.a.v. de heer X. Wei
Koningin Julianaplein 10
2595 AA 's-Gravenhage

Farmatec
Bosbolweg 1
Telfoon
Nijstraat 50
3515 XP Den Haag
T 070 740 6161
info@zuidmiddenfarmatec.nl

Inlichtingen via:
medicce_hulpmiddelen@
mivws.nl

Ons kenmerk:
CIBC 2021-3453

Bijlagen

Uw aanvraag
25 mei 2021

Correspondentie uitsluitend
via Farmatec NL. Het is niet mogelijk om
vermelding van de datum en het
kenmerk van deze brief

Datum: 7 juni 2021
Betreft: notificatie medische hulpmiddelen klasse I

Geachte heer Wei,

Hierbij bevestig ik de ontvangst op 25 mei 2021 van de notificatie van de medische hulpmiddelen klasse I, die bedrijf Andent Dental Co., Ltd., met Europees gemachtigde Lotus NL B.V., als fabrikant overeenkomstig Verordening (EU) 2017/745 (MDR) op de markt wenst te gaan brengen. De producten zijn onder volgend kenmerk geregistreerd. Ik verzoek u om in alle verdere correspondentie over een of meer van deze producten het bijbehorende kenmerk te vermelden en het bij telefoongesprekken bij de hand te houden.

Composite Dispenser Gun
Check Retractor
Photographic Mirror/Dental Mirror
air water syringe tips
Endodontic Instrument
Dental hand kit
Barrier film/sleeves
Vacuum Forming Pressure Sheets Film (geen merknaam)
(NL-CA002-2021-59832)

Dental Applicator
Face Shield
Safety Glasses
Dental Bibs Holder
Suction tips
Dental Tray
Dental Wedge
Orthodontic Instruments
Mixing Tips
Mixing Bowl/Cup/Dish/Spatular (geen merknaam)
(NL-CA002-2021-59831)



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Historie
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中华人民共和国 PEOPLE'S REPUBLIC OF CHINA 医疗器械产品出口销售证明 CERTIFICATE FOR EXPORTATION OF MEDICAL PRODUCTS

证书编号:冀沧药监械出 20230005
Certificate NO.: Certificate of medical device exports made in Cangzhou issued by Hebei Drug Supervision Administration No. 20230005

产品名称: 详见附件
Product(s): Details as per attached list

规格型号: 详见附件
Model: Details as per attached list.

产品注册或备案凭证号: 详见附件
Registration certificate(s): Details as per attached list.

生产企业: 冀州市安登特医疗器械有限公司
Manufacturer: Andent Dental Co., Ltd

生产企业住所: 冀州市齐家务乡寨里村
Address of manufacturer: Zhaili Village, Qijiawu Town, Huanghua City, Hebei province, China

生产许可或备案凭证号: 冀沧食药监械生产备 20160018号
Manufacturing License(s): medical device on file under Cangzhou Food and Drug Supervision Administration, Hebei Province No. 20160018

兹证明上述产品已准许在中国生产和销售。 This is to certify that the above products have been registered to be manufactured and sold in China.

证明有效期至: 2025年12月19日
This certification valid until: Feb.19,2025

备注:
Remark:

