

The Declaration of Conformity

Manufacturer: Ningbo Chinmed Technology Co., Ltd.
Address: NO. 20 Xingzhong Road, Qijiashan Street, Beilun Area, Ningbo, Zhejiang Province, 315803, P.R.China
European Representative: SUNGO Europe B.V.
Address: Olympisch Stadion 24 1076DE Amsterdam, Netherlands
Product Name: Transparent film dressing, Black film dressing
Size Descriptions: (mm): 100x150, 50x1000, 100x1000, 150x1000; 200x1000; special sizes based on customers' request.
Basic UDI-DI / GMDN code: 17-428
UDI-DI / GTIN-13 code Dermalize ROLLS 15cmx10m: 8056093500004
UDI-DI / GTIN-13 code Dermalize PACKS 10x15cm: 8056093500011
UDI-DI / GTIN-13 code D-lizepro ROLLS 15cmx10m: 8056093500028 ; UPC Code: 817934020024
UDI-DI / GTIN-13 code D-lizepro PACKS 10x15cm: 8056093500035 ; UPC Code: 817934020031

UDI-DI / GTIN-13 code Dermalize ROLLS- BLACK sun-block 15cmx10m:8056093500141
UDI-DI / GTIN-13 code Dermalize PACKS- BLACK sun-block 10x15cm: 8056093500158

Classification: Class I, rule 4 of Annex VIII.

Conformity Assessment Route: Annex II+III of REGULATION (EU) 2017/745, it bears the mark



Standards Applied: all applicable standard

We, the manufacturer, herewith declare with sole responsibility that our product/s mentioned above meet/s the provisions of the REGULATION (EU) 2017/745. We agree to develop, implement and maintain a documented post-production monitoring process.

Notified Body: SGS United Kingdom Ltd.
(EC) Certificates: CN15/20782
Expire date of the Certificates: 18th, Jan, 2024
Start of CE marking: 18th, January, 2012
Date of Issue: 4/13/2022

Signature: *For and on behalf of*
宁波市诚德医疗科技有限公司
NINGBO CHINMED TECHNOLOGY CO.,LTD.

韩超

Name: Han Chao(韩超) *Authorized Signature(s)*

Position: Quality manager