TOPPOINT B.V.
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EU Declaration of Conformity (DOC)

Company name:	Toppoint BV
Postal address:	F. Hazemeijerstraat 400 B04
Postcode and City:	7555 RJ Hengelo
Telephone number:	+31 (0)74 207 7955
Central contact point:	toppoint.com/cp

Item number: LT90319
Description: Plaster box with 10 PE plasters (70 × 18 mm)
Country of Origin: China
HS Code: 3006500000

Toppoint B.V. hereby declares this product is manufactured in facilities operating under a **Quality Management System certified in accordance with MDR requirements**.

The kit contains:

- **CE-marked medical devices**, which comply with the applicable requirements of Regulation (EU) 2017/745. The relevant **Declarations of Conformity for these devices are provided in the annex** to this declaration.

This article is in conformity with the following applicable requirements;

Conducted Compliance Testing

REACH Regulation	(EC) 1907/2006
Annex XVII, Entry 63	Total lead content
Annex XVII, Entry 23	Total cadmium content
Annex XVII, Entry 51 & 52	Phthalates content
Annex XVII, Entry 72	Polycyclic Aromatic Hydrocarbons (PAHs)
	Formaldehyde

Part number	Description
1	Translucent black plastic shell
2	Transparent black plastic shell
3	White paper with green printing sheet
4	White paper sheet
5	White fabric sheet
6	Brown plastic with glue body

Signed for and on behalf of:

Place: Hengelo **Date of Issue:** 18/12/2025
Name: Lotte Lutjes
Function: Compliance & Sustainability Specialist
Signature and company stamp:



WE AIM HIGH.

EU Declaration of Conformity

Manufacturer: FIRSTAR HEALTHCARE COMPANY LIMITED (GUANGZHOU)
Address: Rm. 901, Building No.2, Headquarters Center, Tian'an High-tech Ecological Park, Panyu, 511400 Guangzhou, PEOPLE'S REPUBLIC OF CHINA
SRN: CN-MF-000009645

European Representative: MedPath GmbH
Mies-van-der-Rohe-Strasse 8, 80807 Munich, Germany
SRN: DE-AR-000000087

Trade name: PLASTER DRESSING
Product Name: Film Dressing, Adhesive Island Dressing, Adhesive Plaster,
Product code:
FS-3020,FS-3022,FS-3023, FS-3024,FS-3025, *FS-3026A,FS-3026B,FS-3026C,FS-3021, FS-3026D,FS-3026E,FS-3026F,*FS-3040,FS-3042,FS-3043,FS-3044,FS-3045,FS-3047, *FS-3041A,FS-3048A,FS-3041B,FS-3048B,FS-3048C,FS-3048D,FS-3048E*
FS-200F/FS-200P(72×19mm),FS-202F/FS-202P(76×25mm),FS-203F/FS-203P(40×10mm), FS-204F/FS-204P(76×38mm),FS-205F/FS-205P(56×19mm),FS-222F/FS-222P(49×46mm), FS-207F/FS-207P(Φ22mm),FS-208F/FS-208P(38×38mm), FS-209F/FS-209P(40×20mm), FS-189、FS-190
EMDN code: M04010199
Intended use: Act as a barrier, maintain wound position and absorb exudates from the wound.

Applied Standard & Common Specification:
EN 13726-1:2002/AC:2003、EN ISO 14971:2019, EN ISO 14971:2019/A11:2021, EN ISO 13485:2016, EN ISO13485:2016/AC:2018, EN ISO 13485:2016/A11:2021

Basic UDI-DI: See attached.
Classification acc. to MDR Ax .VIII: Class Is, Rule 4
Conformity assessment procedure: Annex XI Part A of MDR(EU)2017/745

Name of the Notified Body: TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße. 65 • 80339, 80339 Munich • Germany
NB Identification number: 0123
CE certificate No: G21 047330 0062 Rev.02
Expiry data of the certificate: 2028-02-08
Start of CE Marking: 2024-08-02

We, the manufacturer, herewith declare under our sole responsibility that the above-mentioned products meet the provisions of the Regulation (EU) 2017/745 on Medical Devices (MDR). All supporting documentations are retained under the premises of the manufacturer.

Attached:
Basic UDI-DI:

Device Name	Models	Basic UDI-DI
Adhesive Plaster	FS-200F	69422726P2.02.02WL
	FS-200P	69422726P2.02.01WJ
	FS-202F	69422726P2.02.02WL
	FS-202P	69422726P2.02.01WJ
	FS-203F	69422726P2.02.02WL
	FS-203P	69422726P2.02.01WJ
	FS-204F	69422726P2.02.02WL
	FS-204P	69422726P2.02.01WJ
	FS-205F	69422726P2.02.02WL
	FS-205P	69422726P2.02.01WJ
	FS-222F	69422726P2.02.02WL
	FS-222P	69422726P2.02.01WJ
	FS-207F	69422726P2.02.02WL
	FS-207P	69422726P2.02.01WJ
	FS-208F	69422726P2.02.02WL
	FS-208P	69422726P2.02.01WJ
	FS-209F	69422726P2.02.02WL
	FS-209P	69422726P2.02.01WJ
	FS-189	69422726P2.02.13WR
	FS-190	69422726P2.02.13WR
	FS-369	69422726P2.02.00WG
Film Dressing	FS-3020	69422726P2.01.00W9
	FS-3022	69422726P2.01.00W9
	FS-3023	69422726P2.01.00W9
	FS-3024	69422726P2.01.00W9
	FS-3025	69422726P2.01.00W9
	FS-3026A	*69422726P2.01.00W9*

	FS-3026B	69422726P2.01.00W9
	FS-3026C	69422726P2.01.00W9
	FS-3021	69422726P2.01.00W9
	FS-3026D	69422726P2.01.00W9
	FS-3026E	69422726P2.01.00W9
	FS-3026F	69422726P2.01.00W9
Adhesive Island Dressing	FS-3040	69422726P2.01.01WB
	FS-3042	69422726P2.01.01WB
	FS-3043	69422726P2.01.01WB
	FS-3044	69422726P2.01.01WB
	FS-3045	69422726P2.01.01WB
	FS-3047	69422726P2.01.01WB
	FS-3041A	69422726P2.01.01WB
	FS-3048A	69422726P2.01.01WB
	FS-3041B	69422726P2.01.01WB
	FS-3048B	69422726P2.01.01WB
	FS-3048C	69422726P2.01.01WB
	FS-3048D	69422726P2.01.01WB
	FS-3048E	69422726P2.01.01WB

Signature: Janice-Li

Name: Janice-Li

Position: QM

Place：Guangzhou

Date：2025-10-20

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