OMC nv
Decauvillestraat 30
8510 Marke - Belgium

www.detectaplast.be
www.protectaplast.be

DECLARATION OF CONFORMITY

Regulation on Medical Devices (EU) 2017/745

This EU Declaration of Conformity is issued under the sole responsibility of Ortho Medic Care NV

Manufacturer

Ortho Medic Care Nv

Decauvillestraat 30
8510 Marke
Belgium

SRN: BE-MF-000019601

BASIC UDI-DI 5430000726009

Product(s)

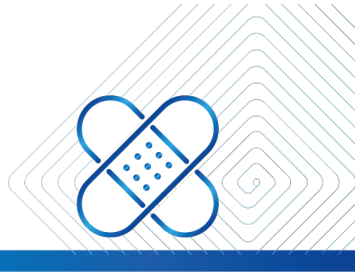
- **DETECTAPLAST® and PROTECTAPLAST® ADHESIVE PLASTERS**

see appendix

The product(s) described above is/ are in conformity with:

Title	
Medical Device Regulation	2017/745

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Additional information

Conformity assessment procedure for CE marking: Medical Device Regulation, Annex V

Registration nr.: BE/CA01/1-12881-MMD-00001

Product standards:

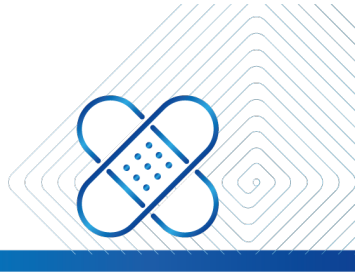
ISO 10993-1
ISO 10993-5
ISO 10993-7
ISO 10993-10
ISO 10993-12
ISO 14644-3,4

Intended purpose; For covering skin scratches and minor wounds.

Kortrijk, 2025/01/09 Wouter Jacobs, Director



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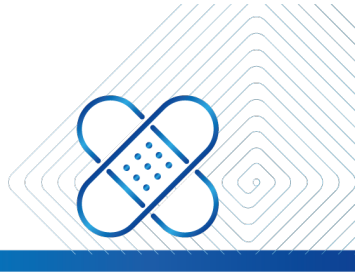
Appendix

Date: 2025-09-01

List of devices.

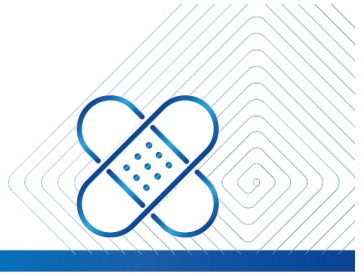
Type/ model/ref number	Device name	Risk class /
8045.10.SIE	PANSEMENT PU BLEU DETECTABLE PAPILLON - 10PCS 076DETEC-10	Class I/ rule 4
8045.100.SIE	PANSEMENT PU BLEU DETECTABLE PAPILLON - 100PCS 076DETEC-100	Class I/ rule 4
8045.50.SIE	PANSEMENT PU BLEU DETECTABLE PAPILLON - 50PCS 076DETEC-50	Class I/ rule 4
8046.10.SIE	PANSEMENT PU BLEU DETECTABLE ARTICULATION - 10PCS 078DETEC-10	Class I/ rule 4
8046.100.SIE	PANSEMENT PU BLEU DETECTABLE ARTICULATION - 100PCS 078DETEC-100	Class I/ rule 4
8046.50.SIE	PANSEMENT PU BLEU DETECTABLE ARTICULATION - 50PCS 078DETEC-50	Class I/ rule 4
8051.10.SIE	PANSEMENT PU BLEU DETECTABLE 50X72MM - 10PCS	Class I/ rule 4
8051.100.SIE	PANSEMENT PU BLEU DETECTABLE 50X72MM - 100PCS 068DETEC-100	Class I/ rule 4
8051.50.SIE	PANSEMENT PU BLEU DETECTABLE 50X72MM - 50PCS	Class I/ rule 4
8056.SIE	PANSEMENT PLASTIQUE BLUE DETECTABLE 8CMX5M- 1PC 003DETEC-5M	Class I/ rule 4
8060.10.SIE	PANSEMENT INTISSE BLANC 19X72mm - 10PCS 036-10	Class I/ rule 4
8060.100.SIE	PANSEMENT INTISSE BLANC 19X72mm - 100PCS 036-100	Class I/ rule 4
8060.50.SIE	PANSEMENT INTISSE BLANC 19X72mm - 50PCS 036-50	Class I/ rule 4
8063.10.SIE	PANSEMENT INTISSE BLANC 38X72 - 10PCS 037-10	Class I/ rule 4
8063.100.SIE	PANSEMENT INTISSE BLANC 38X72 - 100PCS 037-100	Class I/ rule 4
8063.50.SIE	PANSEMENT INTISSE BLANC 38X72 - 50PCS 037-50	Class I/ rule 4
8064.10.SIE	PANSEMENT INTISSE BLANC 50X70MM- 10PCS 068-10	Class I/ rule 4
8064.100.SIE	PANSEMENT INTISSE BLANC 50x72mm - 100PCS 068-100	Class I/ rule 4
8064.50.SIE	PANSEMENT INTISSE BLANC 50X70MM- 50PCS 068-50	Class I/ rule 4
8065.SIE	PANSEMENT INTISSE BLANC 6CMX5M 028-5M	Class I/ rule 4
8068.SIE	PANSEMENT INTISSE BLANC 6CMX1M 028-1M	Class I/ rule 4
80689.10	PANSEMENT INTISSE BLANC 6CMX100MM - 10PCS	Class I/ rule 4
80689.10.SIE	PANSEMENT INTISSE BLANC 6CMX100MM - 10PCS 038-10	Class I/ rule 4
80689.100.SIE	PANSEMENT INTISSE BLANC 6CMX100MM - 100PCS 038-100	Class I/ rule 4

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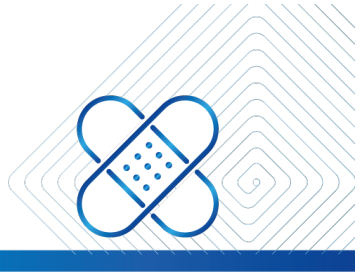
80689.25.SIE	PANSEMENT INTISSE BLANC 6CMX100MM - 25PCS 038-25	Class I/ rule 4
80689.50.SIE	PANSEMENT INTISSE BLANC 6CMX100MM - 50PCS 038-50	Class I/ rule 4
8069.10.SIE	PANSEMENT INTISSE BLANC PAPILLON - 10PCS 076-10	Class I/ rule 4
8069.100.SIE	PANSEMENT INTISSE BLANC PAPILLON - 100PCS 076-100	Class I/ rule 4
8069.50.SIE	PANSEMENT INTISSE BLANC PAPILLON - 50PCS 076-50	Class I/ rule 4
8072.10.SIE	PANSEMENT INTISSE BLANC 38X38MM - 10PCS 067NT-10	Class I/ rule 4
8072.100.SIE	PANSEMENT INTISSE BLANC 38X38MM - 100PCS 067NT-100	Class I/ rule 4
8072.50.SIE	PANSEMENT INTISSE BLANC 38X38MM - 50PCS 067NT-50	Class I/ rule 4
8073.SIE	PANSEMENT INTISSE BLANC 6CMX25M - 1PC 028 - 25M	Class I/ rule 4
8074.SIE	PANSEMENT INTISSE BLANC 8CMX1M - 1PC 030 - 1M	Class I/ rule 4
8075.SIE	PANSEMENT INTISSE BLANC 8CMX5M - 1PC 030 - 5M	Class I/ rule 4
8076.SIE	PANSEMENT INTISSE BLANC 8CMX25M - 1PC 030-25M	Class I/ rule 4
8081.10.SIE	PANSEMENT ENFANT PLASTIQUE - 10PCS 020BB-10	Class I/ rule 4
8081.100.SIE	PANSEMENT ENFANT PLASTIQUE - 100PCS 020BB-100	Class I/ rule 4
8081.50.SIE	PANSEMENT ENFANT PLASTIQUE - 50PCS 020BB-50	Class I/ rule 4
8088.SIE	PANSEMENT PLASTIQUE BLEU DETECTABLE 6CMX1M- 1PC 001BLEU-1M	Class I/ rule 4
8089.SIE	PANSEMENT PLASTIQUE BLEU DETECTABLE 8CMX1M- 1PC 003DETEC-1M	Class I/ rule 4
8090.10.SIE	PANS. EXTENSIBLE NT CHAIR 19X72MM - 10PCS 020ECO-10	Class I/ rule 4
8090.100.SIE	PANS. EXTENSIBLE NT CHAIR 19X72MM - 100PCS 020ECO-100	Class I/ rule 4
8090.50.SIE	PANS. EXTENSIBLE NT CHAIR 19X72MM - 50PCS 020ECO-50	Class I/ rule 4
8093.10.SIE	PANS. EXTENSIBLE NT CHAIR 38X72MM - 10PCS 021ECO-10	Class I/ rule 4
8093.100.SIE	PANS. EXTENSIBLE NT CHAIR 38X72MM - 100PCS 021ECO-100	Class I/ rule 4
8093.50.SIE	PANS. EXTENSIBLE NT CHAIR 38X72MM - 50PCS 021ECO-50	Class I/ rule 4
8094.10.SIE	PANS. EXTENSIBLE NT CHAIR 50X72MM - 10PCS 069ECO-10	Class I/ rule 4
8094.100.SIE	PANS. EXTENSIBLE NT CHAIR 50X72MM - 100PCS 069ECO-100	Class I/ rule 4
8094.50.SIE	PANS. EXTENSIBLE NT CHAIR 50X72MM - 50PCS 069ECO-50	Class I/ rule 4
8095.10.SIE	PANS. EXTENSIBLE NT CHAIR PAPILLON - 10PCS 076ECO-10	Class I/ rule 4
8095.100.SIE	PANS. EXTENSIBLE NT CHAIR PAPILLON - 100PCS 076ECO-100	Class I/ rule 4
8095.20.SIE	PANS. EXTENSIBLE NT CHAIR PAPILLON - 20PCS 076ECO-20	Class I/ rule 4
8095.50.SIE	PANS. EXTENSIBLE NT CHAIR PAPILLON - 50PCS 076ECO-50	Class I/ rule 4
8096.10.SIE	PANS. EXTENSIBLE NT CHAIR ARTICULATION - 10PCS 078ECO-10	Class I/ rule 4
8096.100.SIE	PANS. EXTENSIBLE NT CHAIR ARTICULATION - 100PCS 078ECO-100	Class I/ rule 4
8096.50.SIE	PANS. EXTENSIBLE NT CHAIR ARTICULATION - 50PCS 078ECO-50	Class I/ rule 4
8098.10.SIE	PANS. EXTENSIBLE NT CHAIR 9.5X38MM - 10PCS 019ECO-10	Class I/ rule 4
8098.100.SIE	PANS. EXTENSIBLE NT CHAIR 9.5X38MM - 100PCS 019ECO-100	Class I/ rule 4
8098.50.SIE	PANS. EXTENSIBLE NT CHAIR 9.5X38MM - 50PCS 019ECO-50	Class I/ rule 4

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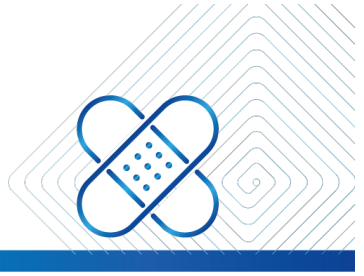
8112.SIE	PANSEMENT TISSU ROSE ELASTIQUE 6CMX1M 001-1M	Class I/ rule 4
8114.SIE	PANSEMENT TISSU ROSE ELASTIQUE 4CMX5M 005-5M	Class I/ rule 4
8115.SIE	PANSEMENT TISSU ROSE ELASTIQUE 6CMX5M 001-5M	Class I/ rule 4
8116.SIE	PANSEMENT TISSU ROSE ELASTIQUE 8CMX5M 003-5M	Class I/ rule 4
8117.SIE	PANSEMENT TISSU ROSE ELASTIQUE 6X25CM - 1 PC 001-25M	Class I/ rule 4
8118.SIE	PANSEMENT TISSU ROSE ELASTIQUE 8 X 1M - 1 PC 003-1M	Class I/ rule 4
8119.SIE	PANSEMENT TISSU ROSE ELASTIQUE 8 X 25M - 1 PC 003-25M	Class I/ rule 4
8120.10.SIE	PANSEMENT TISSU ROSE ELASTIQUE 19X72MM - 10PCS 020-10	Class I/ rule 4
8120.100.SIE	PANSEMENT TISSU ROSE ELASTIQUE 19X72MM - 100PCS 020-100	Class I/ rule 4
8120.50.SIE	PANSEMENT TISSU ROSE ELASTIQUE 19X72MM - 50PCS 020-50	Class I/ rule 4
8125.10.SIE	PANSEMENT TISSU ROSE ELASTIQUE PAPILLON - 10PCS 076ROSE-10	Class I/ rule 4
8125.100.SIE	PANSEMENT TISSU ROSE ELASTIQUE PAPILLON - 100PCS 076ROSE-100	Class I/ rule 4
8125.50.SIE	PANSEMENT TISSU ROSE ELASTIQUE PAPILLON - 50PCS 076ROSE-50	Class I/ rule 4
8126.10.SIE	PANSEMENT TISSU ROSE ELASTIQUE ARTICULATION - 10PCS 078-10	Class I/ rule 4
8126.100.SIE	PANSEMENT TISSU ROSE ELASTIQUE ARTICULATION - 100PCS	Class I/ rule 4
81289.10.SIE	PANSEMENT TISSU ROSE ELASTIQUE 18X2CM - 10PCS 022-10	Class I/ rule 4
81289.100.SIE	PANSEMENT TISSU ROSE ELASTIQUE 18X2CM - 100PCS	Class I/ rule 4
81289.50.SIE	PANSEMENT TISSU ROSE ELASTIQUE 18X2CM - 50PCS 022-50	Class I/ rule 4
8130.10.SIE	PANSEMENT TISSU ROSE ELASTIQUE 38X72MM - 10PCS 072-10	Class I/ rule 4
8130.100.SIE	PANSEMENT TISSU ROSE ELASTIQUE 38X72MM - 100PCS 072-100	Class I/ rule 4
8130.50.SIE	PANSEMENT TISSU ROSE ELASTIQUE 38X72MM - 10PCS 072-10	Class I/ rule 4
8131.10.SIE	PANSEMENT TISSU ROSE ELASTIQUE 38X38MM - 10PCS 067-10	Class I/ rule 4
8131.100.SIE	PANSEMENT TISSU ROSE ELASTIQUE 38X38MM - 100PCS 067-100	Class I/ rule 4
8131.50.SIE	PANSEMENT TISSU ROSE ELASTIQUE 38X38MM - 50PCS 067-50	Class I/ rule 4
8140.10.SIE	PANSEMENT DETECTABLE PLASTIQUE BLEU 19X72MM - 10PCS 020DETEC-10	Class I/ rule 4
8140.100.SIE	PANSEMENT DETECTABLE PLASTIQUE BLEU 19X72MM - 100PCS 020DETEC-100	Class I/ rule 4
8140.50.SIE	PANSEMENT DETECTABLE PLASTIQUE BLEU 19X72MM - 50PCS 020DETEC-50	Class I/ rule 4
8143.10.SIE	PANSEMENT DETECTABLE PLASTIQUE BLEU 38X72MM - 10PCS 070DETEC-10	Class I/ rule 4
8143.100.SIE	PANSEMENT DETECTABLE PLASTIQUE BLEU 38X72MM - 100PCS 070DETEC-100	Class I/ rule 4
8143.50.SIE	PANSEMENT DETECTABLE PLASTIQUE BLEU 38X72MM - 50PCS 070DETEC-50	Class I/ rule 4
81489.10.SIE	PANSEMENT DETECTABLE PLASTIQUE BLEU 180X20MM - 10PCS 022DETEC-10	Class I/ rule 4
81489.100.SIE	PANSEMENT DETECTABLE PLASTIQUE BLEU 180X20MM - 100PCS 022DETEC-100	Class I/ rule 4
81489.50.SIE	PANSEMENT DETECTABLE PLASTIQUE BLEU 180X20MM - 50PCS 022DETEC-50	Class I/ rule 4
8150.SIE	PANSEMENT PLASTIQUE ROSE 6cmx1m 001PL-1M	Class I/ rule 4
8151.SIE	PANSEMENT PLASTIQUE ROSE 6cmx5m 001PL-5M	Class I/ rule 4
8152.SIE	PANSEMENT PLASTIQUE ROSE 6cmx25m 001PL-25M	Class I/ rule 4
8153.SIE	PANSEMENT PLASTIQUE ROSE 8CMx1M 003PL-1M	Class I/ rule 4

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81535.SIE	PANSEMENT PLASTIQUE ROSE 8cmx5m 003PL-5M	Class I/ rule 4
8157.10.SIE	PANSEMENT PLASTIQUE ROSE 38X38MM - 10PCS 067PL-10	Class I/ rule 4
8157.100.SIE	PANSEMENT PLASTIQUE ROSE 38X38MM - 100PCS 067PL-100	Class I/ rule 4
8157.50.SIE	PANSEMENT PLASTIQUE ROSE 38X38MM - 50PCS 067PL-50	Class I/ rule 4
8158.10.SIE	PANSEMENT PLASTIQUE ROSE 38X72MM - 10PCS 070PL-10	Class I/ rule 4
8158.100.SIE	PANSEMENT PLASTIQUE ROSE 38X72MM - 100PCS 070PL-100	Class I/ rule 4
8158.50.SIE	PANSEMENT PLASTIQUE ROSE 38X72MM - 50PCS 070PL-50	Class I/ rule 4
8170.10.SIE	PANSEMENT PLASTIQUE ROSE 19X72MM - 10PCS 020PL-10	Class I/ rule 4
8170.100.SIE	PANSEMENT PLASTIQUE ROSE 19X72MM - 100PCS 020PL-100	Class I/ rule 4
8170.50.SIE	PANSEMENT PLASTIQUE ROSE 19X72MM - 50PCS 020PL-50	Class I/ rule 4
8189.SIE	PANSEMENT TISSU BLEU DETECTABLE 1M X 8CM 003BLEUCOT-1M	Class I/ rule 4
8191.10.SIE	PANSEMENT PU ETANCHE RESPIRANT 25X72MM - 10PCS 020PU-10	Class I/ rule 4
8191.100.SIE	PANSEMENT PU ETANCHE RESPIRANT 25X72MM - 100PCS 020PU-100	Class I/ rule 4
8191.50.SIE	PANSEMENT PU ETANCHE RESPIRANT 25X72MM - 50PCS 020PU-50	Class I/ rule 4
8195.10.SIE	PANSEMENT PU ETANCHE RESPIRANT 50X72MM - 10PCS 069PU-10	Class I/ rule 4
8195.50.SIE	PANSEMENT PU ETANCHE RESPIRANT 50X72MM - 50PCS 069PU-50	Class I/ rule 4
8240.10.SIE	PANSEMENT TISSU BLEU DETECTABLE 19X72MM - 10PCS 023BLEUCOT-10	Class I/ rule 4
8240.100.SIE	PANSEMENT TISSU BLEU DETECTABLE 19X72MM - 100PCS 023BLEUCOT-100	Class I/ rule 4
8240.50.SIE	PANSEMENT TISSU BLEU DETECTABLE 19X72MM - 50PCS 023BLEUCOT-50	Class I/ rule 4
8245.10.SIE	PANSEMENT TISSU BLEU DETECTABLE PAPILLON - 10PCS 076BLEUCOT-10	Class I/ rule 4
8245.100.SIE	PANSEMENT TISSU BLEU DETECTABLE PAPILLON - 100PCS 076BLEUCOT-100	Class I/ rule 4
8245.50.SIE	PANSEMENT TISSU BLEU DETECTABLE PAPILLON - 50PCS 076BLEUCOT-50	Class I/ rule 4
8251.10.SIE	PANSEMENT TISSU BLEU DETECTABLE 50X72MM - 10PCS 071BLEUCOT-10	Class I/ rule 4
8251.100.SIE	PANSEMENT TISSU BLEU DETECTABLE 50X72MM - 100PCS 071BLEUCOT-100	Class I/ rule 4
8251.50.SIE	PANSEMENT TISSU BLEU DETECTABLE 50X72MM - 50PCS 071BLEUCOT-50	Class I/ rule 4
8256.SIE	PANSEMENT TISSU BLEU DETECTABLE 5M X 8CM	Class I/ rule 4
8258.SIE	PANSEMENT TISSU BLEU DETECTABLE 25M X 8CM 003BLEUCOT-25M	Class I/ rule 4
83489.10.SIE	PANSEMENT TISSU BLEU DETECTABLE 18X2CM 022BLEUCOT-10	Class I/ rule 4
83489.100.SIE	PANSEMENT TISSU BLEU DETECTABLE 18X2CM 022BLEUCOT-100	Class I/ rule 4
83489.50.SIE	PANSEMENT TISSU BLEU DETECTABLE 18X2CM 022BLEUCOT-50	Class I/ rule 4
PAN01-100T14	PANS. TISSU ROSE ELASTIQUE MIX 50PCS PAN01-50-T14	Class I/ rule 4
PAN01-T11	PANS. TISSU ROSE ELASTIQUE ASSORT. 20PCS PAN01-T11	Class I/ rule 4
PAN02-50	PANS. DETECTABLE PLASTIQUE BLUE ASSORT. - 50PCS PAN02-50	Class I/ rule 4
PAN02-T13	PANS. DETECTABLE PLASTIQUE BLUE ASSORT. - 20PCS PAN02-T13	Class I/ rule 4
PAN06-100-T14	PANS. PLASTIQUE ASSORT. - 100PCS PAN06-100-T14	Class I/ rule 4
PAN06-50-T14	PANS. PLASTIQUE ASSORT. - 50PCS PAN06-50-T14	Class I/ rule 4

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PAN06-T13	PANS. PLASTIQUE ASSORT. - 22PCS PAN06-T13	Class I/ rule 4
PAN07	PANS. EXTENSIBLE NT CHAIR ASSORT. - 20PCS PAN07	Class I/ rule 4
PAN07-10	PANS. EXTENSIBLE NT CHAIR ASSORT. - 11PCS PAN07-10	Class I/ rule 4
PAN07-100	PANS. EXTENSIBLE NT CHAIR ASSORT. - 100PCS PAN07-100	Class I/ rule 4
PAN07-30	PANS. EXTENSIBLE NT CHAIR ASSORT. - 30PCS PAN07-30	Class I/ rule 4
PAN07-50	PANS. EXTENSIBLE NT CHAIR ASSORT. - 50PCS PAN07-50	Class I/ rule 4
PAN07-6T-T18	PANS. EXTENSIBLE NT CHAIR ASSORT. - 20PCS PAN07-6T-T18	Class I/ rule 4
PAN07-TREMBLAY	PANS. EXTENSIBLE NT CHAIR TREMBLAY -30PCS	Class I/ rule 4
PAN14-100T14	PANS. EXTENSIBLE NT BLANC ASSORT. - 100PCS PAN14-100T14	Class I/ rule 4
PAN14-50-T14	PANS. EXTENSIBLE NT BLANC ASSORT. - 20PCS PAN14-T11	Class I/ rule 4
PANACHE06	PANS. TISSU ROSE ELASTIQUE - 12PCS PANACHE06	Class I/ rule 4
PANACHE100ECO	PANS. EXTENSIBLE NT CHAIR ASSORT. - 100PCS PANACHE100ECO	Class I/ rule 4
PANACHE10ECO	PANS. EXTENSIBLE NT CHAIR ASSORT. - 10PCS PANACHE10ECO	Class I/ rule 4
PANACHE10PL	PANS. PLASTIQUE ROSE - 10PCS PANACHE10PL	Class I/ rule 4
PANACHE120ECO	PANS. EXTENSIBLE NT CHAIR ASSORT. - 120PCS PANACHE120ECO	Class I/ rule 4
PANACHE12ECO	PANS. EXTENSIBLE NT ASSORT. - 12PCS PANACHE12ECO	Class I/ rule 4
PANACHE20PL	PANS. PLASTIQUE ROSE - 20PCS PANACHE20PL	Class I/ rule 4
PANACHE20PU	PANS. ETANCHES RESPIRANTS - 20PCS PANACHE20PU	Class I/ rule 4
PANACHE21ECO	PANS. EXTENSIBLE NT CHAIR ASSORT. - 21PCS PANACHE21ECO	Class I/ rule 4
PANACHE30ECO	PANS. EXTENSIBLE NT CHAIR ASSORT. - 30PCS PANACHE30ECO	Class I/ rule 4
PANACHE30-PARIS	PANS. EXTENSIBLE NT CHAIR ASSORT. - 30PCS PANACHE30-PARIS	Class I/ rule 4
PANACHE30PU	PANS. ETANCHES RESPIRANTS - 30PCS PANACHE30PU	Class I/ rule 4
PAN01-50-T14	PANS. TISSU ROSE ELASTIQUE MIX 50PCS PAN01-50-T14	Class I/ rule 4
PAN01DETEC	ASSORTIMENT PANSEMENT TISSU BLEU DETECTABLE -200PCS PAN01DETEC	Class I/ rule 4