Technical Datasheet: Kinesiology tape / (sensor) patches – MSDS sheet – EU MDR/FDA approved *(Class I Medical Device)*

1. **Product Specification**

Section 1: Product

- **Product Name**: Kinesiology (senor) patches tape (printed and non-printed)
- **Description**: The tape is a premium-quality elastic kinesiology tape, the special cotton structure leads to high stretching properties. It has a hypoallergenic, breathable acrylate adhesive. It is latex-free, water-resistant, contains no medicinal substances, and can be comfortably worn for several days.
- **Material Composition**: Cotton (95%), Acrylic adhesive (5%)
- **Intended use**: Designed to be applied on the skin. They are suitable for the fixation and targeted support.
- **Colour Options**: multiple colours (some are printed)
- **Basic UDI**: 871762416elastic-tapeWX
- **Dimensions**: Oval and circle (see product guide attached)
- **Sterilization Method**: Not sterilized (non-invasive device, intended for external use)
- **Storage Conditions**: Do not store in direct sunlight or near heat sources, keep in cool/ dry place.
- **Transport Conditions**: Avoid exposure to direct sunlight and extreme temperatures during transport.
- **Expiry Date**: 3 years from the manufacturing date when stored under proper conditions.

Material Characteristics Kinesiology Tape and (sensor) patches

Product component:	**Material composition**
Elastic tape material:	95% Cotton und 5% Spandex (Elastane)
Adhesive coating:	pressure sensitive acrylic adhesive, breathable
Release paper:	coated paper

Section 2: Ingredients and characteristics

Product Characteristics Kinesiology Tape and (sensor) patches

Property	**Characteristics**
Construction and dimensions:	Circle and oval
Elongation:	180±30 %
Adhesive coating:	transparent

Coat weight:	45-55 g/m²
Peel adhesion	3-12 N/25mm
Storage/Transport conditions:	no storage permanently above room temperature
Shelf life:	3 years

(Technical modification subject to change)

Ingredient(s)	CAS No.
1. Support Material Cotton, Polyurethane	Non Hazardous Material
2. Adhesive Acrylic Co Polymer	Non Hazardous Material
3. Release Paper High Quality Substrate	Non Hazardous Material

Hazardous Ingredient(s)

1. Paints, preservations, and solvents:	None
2. Alloys and metallic coatings:	None
3. Hazardous mixtures of other liquids, or gases	None

Section 3: Physical Data

Boiling Point (degrees F)	N/A
Vapor Pressure	N/A
Vapor Density (air=1)	N/A
Solubility in Water	Insoluble in water
Specific gravity	N/A
% volatile by volume	NONE
Evaporation rate	N/A
Odor Threshold	N/A
Appearance	See brochure for colours

Section 4: Fire and Explosion Hazard Data

Flash point:	N/A
Flammable limits:	N/A
Extinguishing media:	Class B, C
Special fire fighting procedures:	N/A
Unusual fire and explosion hazard:	N/A

Section 5: Health Hazard Data

Threshold value:	N/A
Effects of overexposure:	None
Emergency and first aid procedures:	None

Section 6: Reactivity Data

Stability:	Stable
Conditions to avoid:	N/A
Incompatibility:	N/A
Hazardous decomposition products:	None
Hazardous polymerization:	Will not occur

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Section 7: Spill or Leak Procedures

Steps to be taken in case material is released or spilled:	N/A

Section 8: Special Protection Information

Respiratory protection:	None
Ventilation:	Adequate
Protective gloves:	No
Eye Protection:	Do not get into eyes
Other protection equipment:	None needed

Section 9: Various

1. Certificates

- **CE Certificate**: Class I non-sterile medical device.
- **ISO 13485-2016 Certification**: IGC (MSCB-105) No. 21-B-0411 Rev.0
- **Other Certificates**: ISO 14001-2015 and ISO 9001-2015

2. Declaration of Conformity

- **Legal Manufacturer**: THYSOL GROUP BV, Josink Kolkweg 18, 7545 PR, Enschede, The Netherlands
- **COO:** Republic of Korea.
  GMDN Code: 10284
- **GMDN code**: M0304020301
- **Risk Class**: Class I (non-sterile, non-measuring)
- **Conformity Standard**: Compliant with EU Medical Device Regulation (MDR) 2017/745.

3. Label Template

- **CH Importer**: IVF Hartmann AG
- **Legal Manufacturer:** THYSOL GROUP BV, Josink Kolkweg 18, 7545 PR, Enschede, The Netherlands
- **CH REP**: Confinis ch-rep ag Hauptstrasse 16CH-3186 Düdingen, Switzerland

4. Instructions for Use (see also insert/IFU attached)

- **INSTRUCTIONS FOR USE:** Apply to clean, dry skin, Gently rub after application for proper adhesion, Remove gradually in the direction of hair growth, Consider using a tape remover if removal is difficult.
- **Restrictions**: Do not apply on open wounds or irritated skin. Do not use if allergic to adhesive materials.
- **Flammability**: Product is non-flammable under normal conditions but should be kept away from open flames.

- **Cleaning/Washing Instructions**: The tape is for single-use and should not be washed or reused.

Warnings/Precautions (see also insert)

- See attached IFU

5. Storage and Transport Conditions

- **Storage Temperature**: Do not store in direct sunlight or near heat sources, keep in cool/dry place. Keep out of reach of children.
- **Humidity Range**: Less than 70% relative humidity
- **Transport**: Protect from direct sunlight and avoid exposure to extreme temperatures during transit.

6. Various

Single Use Device

Reusing a single-use medical device is dangerous. Reprocessing devices, in order to reuse them, may seriously damage their integrity and their performance. Information available on request.

Product Disposal

To minimize the risk of potential infection hazards, or environmental pollution, disposable components of the product should follow disposal procedures according to applicable and local laws, rules, regulations and infection prevention standards.

Packaging Materials All packing materials and packing components are conform to the relevant essential requirements (specific to manufacturing and composition, reusable nature and recoverable nature of packing) of the Packaging and Packaging Waste Directive 94/62/EC and amended directive 2004/12/EC respectively.

Incident Reporting

For a patient/user/third party in the European Union and in countries with identical regulatory regime (Regulation 2017/745/EU on Medical Devices); if, during the use of this device or as a result of its use, a serious incident has occurred, please report it to the manufacturer and/or its authorised representative and to your national authority.

Economical factors

LM	**EU REP**
THYSOL GROUP BV Josink Kolkweg 18 7545 PR Enschede The Netherlands	FYSIOTAPE BV Josink Kolkweg 18 7545 PR Enschede The Netherlands
CH REP	**CH IMPORTER**
CONFINIS CH-REP AG Hauptstrasse 16 CH-3186 Düdingen Switzerland	IVF Hartmann AG Victor-von-Bruns-Strasse 28 CH-8212 Neuhausen, Switzerland

Products Kinesiology tape / (sensor) patches

See CE Form

Additional Information:

- Documents along with the TDS; CE documentation, insert(s), packaging files, product brochures.
- Appendix: Sensor insert/IFU2025

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