USER INFORMATION

Product name : Intouch Powdered (INTW01)

Product type : Sterile Powdered Latex Surgical Gloves (natural colored)

Available size : 5½, 6, 6½, 7, 7½, 8, 8½, 9

Manufacturer : Kossan International Sdn Bhd

Address : Wisma Kossan, Lot 782,
Jalan Sungai Putus, Off Batu 3¾,
Jalan Kapar, 42100 Klang,
Selangor Darul Ehsan, Malaysia

1. Medical Device Directive (MDD)

a. This product is **Class IIa** under Council Directive 93/42/EEC, Annex IX Classification Criteria per Rule 6 and 7.
b. This product complies with European Standards EN 455-1:2000, EN 455-2:2015, EN 455-3:2015, and EN 455-4:2009.

2. Indication for Use (IFU)

Surgical gloves are intended to be used once in an invasive procedure involving a single patient and permanently discarded after use. These gloves are to be worn on the hands of healthcare personnel to provide barrier protection from cross contamination between patient and the healthcare personnel.

3. Usage

For single use only. If re-used:

a. Lost of sterility
b. Extremely high risk of cross-contamination
c. Deterioration of barrier protection
d. Deterioration of glove's properties
e. Lost of lot traceability

4. Contraindications

Healthcare personnel and patients who are allergy to chemicals and latex protein should avoid contact with rubber latex gloves.

5. **Warnings**
   a. This product contains natural rubber latex which may cause allergic reactions, including anaphylactic responses.
   b. Surface powder shall be removed aseptically prior to undertaking operative procedures in order to minimize the risk of adverse tissue reactions.
   c. Do not use if the sealed pouch is punctured, torn, or otherwise compromised.
   d. Do not use if the glove is visibly torn, frayed, or damaged.
   e. Do not re-sterilize.

6. **Storage conditions**
   Store under cool and dry conditions. Avoid direct sunlight, and heat. The gloves are packed in dispenser suitable for transportation. Keep the gloves in the box when they are not in use.

7. **Instruction for Use**
   a. For maximum comfort, choose the fitting gloves size for your hands. Donning the correct glove size reduces hand fatigues/strain since surgical gloves are hand-specific.

   b. Donning:
      - Prior to donning, perform surgical hand scrub using antimicrobial solution and water.
      - When donning, follow “closed donning” method as described below.

   c. Discard the soiled gloves and change to new gloves immediately:
      - As soon as any damage, puncture or tear (or non-integrity is suspected) is noticed.
      - After inadvertent contact with contaminated or non-sterile surface.

   d. Users are recommended to change gloves hourly for surgical procedures more than 60 minutes to reduce the risk of barrier protection failure.

   e. These gloves have not been tested against chemotherapy drugs.

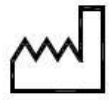
8. **Precaution for disposal**
   Dispose of soiled surgical gloves in accordance with relevant regulations that practice safe disposal of clinical waste.

9. **Closed donning method**
   Step 1: Remove the inner wrap from the pouch carefully without creasing the inner wrap.
   Step 2: Gently lift the right and left side of the inner wrap.
   Step 3: Unflap the inner wraps from the corner.

   Right hand donning:
   Step 4: Use your left hand to pick the glove on the right side by holding the cuff.
   Step 5: Gently slip your fingertips into the glove, stretch the cuff over the fingers until it fits snugly over the hand.

   Left hand donning:
   Step 6: Use your right hand to pick the left-side of the glove by the cuff.
   Step 7: Gently slip your fingertips into the glove, stretch the cuff over the fingers until it fit snugly over the hand.

10. Symbol Used

Symbol	Title of Symbol	Description / Requirements	Information
	Manufacturer	Indicates the medical device manufacturer, as defined in EU Directives 93/42/EEC. This symbol shall be accompanied by the name and address of the manufacturer (i.e. the person placing the medical device on the market), adjacent to the symbol.	 Made in Malaysia for: **Kossan International Sdn. Bhd.** Wisma Kossan, Lot 782, Jalan Sungai Putus, Off Batu 3¾, Jalan Kapar, 42100 Klang, Selangor, Malaysia. Tel: +603-3291 2657 Fax: +603-3392 3699 Made in Malaysia by: **Wear Safe (Malaysia) Sdn. Bhd.** Lot 5068 & 5069, Batu 4½, Jalan Meru, 41050 Klang, Selangor, Malaysia. Tel: +03-3392 1388 / 1328 Fax: +03-33923699 / 2733
	Authorized representative in the European Community	Indicates the Authorized Representative in the European Community. This symbol shall be accompanied by the name and address of the authorized representative in the European Community, adjacent to the symbol.	 **OBERLIS S.A.** Boulevard General Wahis 53, 1030 Brussels, Belgium. Tel: +(32)2.732.59.54 Fax: +(32)2.732.60.03
	Date of manufacture	Indicates the date when the medical device was manufactured. This symbol shall be accompanied by a date to indicate the date of manufacture. This shall be expressed as in ISO 8601 as four digits for the year and, where appropriate, two digits for the month and two digits for the day. The date shall be located adjacent to the symbol.	 2020-02-15

Symbol	Title of Symbol	Description / Requirements	Information
	Use-by date	Indicates the date after which the medical device is not to be used. This symbol shall be accompanied by a date to indicate that the medical device should not be used after the end of the year, month or day shown. The date shall be expressed as in ISO 8601 as four digits for the year and, where appropriate, two digits for the month and two digits for the day. The date shall be located adjacent to the symbol.	 2025-01-15
	Batch code	Indicates the manufacturer's batch code so that the batch or lot can be identified. This symbol shall be accompanied by the manufacturer's batch code. The batch code shall be adjacent to the symbol.	 2020-280 W5
	Do not re-use	Indicates a medical device that is intended for one use, or for use on a single patient during a single procedure.	For single use only
	Latex	Indicates a medical device contains natural rubber latex.	Contain natural rubber latex
CE2797	CE mark	Indicates CE mark with Notified Body number. The CE marking must be accompanied by the identification number of the notified body. The CE marking must have substantially the same vertical dimension, which may not be less than 5 mm.	CE2797
	Keep dry	Indicates a medical device that needs to be protected from moisture.	Store under dry condition.
	Keep away from sunlight	Indicates a medical device that needs protection from light sources.	Avoid direct sunlight and heat.

Symbol	Title of Symbol	Description / Requirements	Information
STERILE R	Sterilized using irradiation	Indicates a medical device that has been sterilized using irradiation.	Gamma Irradiation
	Do not use if package is damaged	Indicates a medical device that should not be used if the package has been damaged or opened.	Do not use if the product sterile barrier system or its packaging is compromised.

Note: This User Information is part of marketing package and intended to provide general guideline only.

11. Shelf Life

Refer to packaging for the manufacturing and expiry dates.