# HARTMANN

#### **Technical Data Sheet**

# Soft-Zellin®

#### **MEDICAL DEVICE**

#### **General Product Description/Intended Purpose**

Soft-Zellin® is an alcohol swab made of nonwoven fabric, impregnated with isopropyl alcohol (70% v/v) ready to use for intact skin surface and is Non-invasive.

Intended user: For use by healthcare professionals and lay-user

Medical device class: I non-sterile, based on Rule 1 of Annex VIII of the Regulation (EU) 2017/745.

#### Application/Indication

Soft-Zellin® is intended for skin cleaning prior to subcutaneous injections and the taking of capillary blood samples. Isopropyl alcohol has cleaning properties by wiping over the skin it cleanses the skin in this area.

Applicable site: Unbreached skin

Open the primary paper bag packaging, take the Alcohol Pad out, use it to wipe intact skin surface for cleaning. If the Alcohol Pads become dry out or dirty change to a new one.

When using Alcohol pad it must be ensured that the applied alcohol has evaporated completely before continuing.

#### **Catalogue Numbers**

Ref	Name	Size (mm)	Pieces per pouch	Pouch per Folding Box	Folding Boxes per transport carton
4110020	Alcohol Pads	60x30	1	100	70

#### Residual Risks, Contra-Indications and Undesirable Side Effects, Warnings

The use of Alcohol pad does not replace disinfection. If the injection point is very dirty, it should first be washed thoroughly with soap and water.

Avoid eye contact.

Keep out of reach of children.

Check the primary foil bag before using, do not use product if bag is opened or damaged.

### **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 Soft-Zellin® should follow disposal procedures according to applicable and local laws, rules, regulations and infection prevention standards.

#### **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 authorized representative and to your national authority.



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#### **Material Characteristics**

Material	45(±3)g/m² non-woven, 50% Rayon + 50% polyester
Size of swab	$30 \times 60 \ (\pm 2)$ mm, impregnated with 70% isopropyl alcohol, and then folded one time into a size of $30 \times 30 \ (\pm 2)$ mm.
Primary packing	Aluminum compound foil pouch

#### Labelling

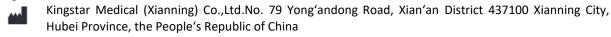
#### Lot-No. with 9-Digit Code e.g.:

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e.g.	$\mathbb{A}$	2015	04	01
		year	month	day
<u>Use-by-Date</u>				
e.g.	22	2020	04	01
		year	month	day

#### Legal Manufacture:



QS Engineering AG, Erlenstrasse 31 CH-4106, Therwil, Switzerland

Shanghai International Holding Corp. GmbH (Europe)Eiffestraße 80 20537 HAMBURG, GERMANY

## <u>Distributior/Importer</u>



PAUL HARTMANN AG, Paul-Hartmann-Straße 12, 89522 HEIDENHEIM, GERMANY IVF HARTMANN AG, Victor-von-Bruns-Strasse 28, 8212 Neuhausen, Switzerland

Shelf Life: 5 years

MD Medical Device

UDI Unique Device Identifier (UDI)

Inflammable

Latest Date of Revision: 2022-10-12