



Island Polymer Industries GmbH
Andresenstr. 6
06766 Bitterfeld-Wolfen, OT Wolfen
Germany

A MEMBER OF



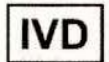
ISLAND GROUP ENTERPRISES

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Multifunctional Coverslipping Film

... made in Germany



**GEBRAUCHSANWEISUNG
INSTRUCTIONS FOR USE
NOTICE D'UTILISATION**



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Island Polymer Industries GmbH

EU Konformitätserklärung / EC Declaration of Conformity

Nr. / No.:

IPI-EC-PT/2022-V01

Name und Adresse des Unternehmens / name and address of the company:

Island Polymer Industries GmbH
Andresenstr. 6
06766 Bitterfeld-Wolfen, OT Wolfen
Deutschland / Germany

Single Registration Number (SRN):

DE-MF-000011884

Produkt- u. Handelsname / product and trade name:

IPI Pathotape®

Basis UDI-DI / basic UDI-DI:

426060659CSFPT1AGC

Risikoklasse / risk class:

A

Wir erklären als Hersteller in alleiniger Verantwortung, dass das IVD-Medizinprodukt **IPI Pathotape®** / We declare as the manufacturer in sole responsibility that the IVD medical device **IPI Pathotape®**

verwendbar ist als / could be used as

Eindeckfolie für Eindeckautomaten in der Pathologie /
coverslipping film for automatic coverslippers in the
pathology

und allen relevanten Anforderungen der VERORDNUNG (EU) 2017/746 DES EUROPÄISCHEN PARLAMENTS UND DES RATES vom 05. April 2017 über In-vitro-Diagnostika und der unten aufgeführten Normen und normativen Dokumente entspricht, die anwendbar sind / meets all relevant provisions of the Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices and the below listed standards and normative documents, which apply to it.

Angewandte harmonisierte Normen, nationale Normen oder andere normative Dokumente / Applied harmonized standards, national standards or other normative documents:

Medizinproduktegesetz (MPG),
IVDR (EU) 2017/746,
DIN EN ISO 9001:2015,
DIN EN ISO 13485:2016,
DIN EN ISO 14971:2019,
DIN EN ISO/IEC 17050-1:2010,
Directive 2011/65/EC (RoHS)

Konformitätsbewertungsverfahren / conformity assessment procedure:

nach Artikel 48, Absatz 10 der Verordnung (EU) 2017/746 über In-vitro-Diagnostika / according to Article 48, paragraph 10 of Regulation (EU) 2017/746 on in vitro diagnostic medical devices

Diese Erklärung gilt für Produkte, die ab dem Datum der Ausstellung in Verkehr gebracht werden. / This declaration applies to products placed on the market from the date of issue.


Ort, Datum / place, date:

Wolfen, May 16, 2022

Unterzeichnet für und im Namen von: / signed for and on behalf of:

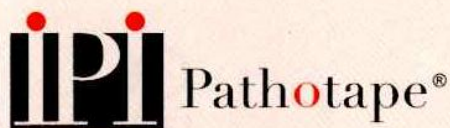

Gernod Härter

Geschäftsführer / General Managing Director


Silvio Böttcher

Sicherheitsbeauftragter für Medizinprodukte / Safety Officer
for Medical Products

INSTRUCTIONS FOR USE / PRODUCT INFORMATION



Product Description:

- The high quality IPI Pathotape® coverslipping film could be used together with Xylene in all actually available automated film coverslippers.
- The special – patent filed - surface structure allows a homogenous distribution of solvent drops and an improved long term adhesion without any effects on the high transparency of the film after the coverslipping procedure.
- The coverslipping film is 100% made in Germany and developed, manufactured and quality controlled according to DIN EN ISO 13485 and under the restrictions of (certified) DIN EN ISO 9001/14001/50001.
- Based on the German law for medical products a conformity assessment procedure according to annex III of the directive on in vitro diagnostic medical devices 98/79/EC was conducted and an EC declaration of conformity was established for the **IPI Pathotape®** coverslipping film.
- The usable film length of 70 meters allows an automatic coverslipping of 1.400 slides (à 50 mm).

Safety Information:

- If the product is used in accordance with the manual, and the general laboratory safety and hygiene regulations are taken into account and are respected, this product does not present any direct danger. Given that the film is relatively thin and stiff and is cut off the roll in the coverslipping machine by a blade cut, the resulting cut edges may carry a risk of injury by improper handling. This risk would be minimized by wearing protective gloves and careful handling of the product.
- Please read also the safety data sheet, which could be obtained from your local distribution partner or from our website.

Film Transport Conditions:

- Transport the packaged film rolls in a temperature range of 5°C to 35°C and a relative humidity between 30% and 70%. Avoid direct sunlight exposure, direct water contact and long term exposure to temperatures over 35°C (40°C max. 24 hrs).
- The outer 5 rolls case box is labeled with a temperature sensitive sticker, which has an irreversible switching point at 40°C. If the sticker label has changed its color into black please contact your local supplier.

Storage Conditions Before Coverslipping:

- Store the sealed film rolls at temperatures between 5°C and 30°C and humidity levels of 30% to 70%. For long term storage a temperature range between 15°C and 25°C is recommended.
- It is important to know that long term storage above temperatures of 30°C could cause a reduction of the functional surface structure, a film deformation and a reduced adhesion between the film and the slide accompanied by an increased number of bubbles.

Operating Conditions:

- It is recommended to completely remove the plastic bag after opening and allow the film to acclimate to the environment at least 2 hours prior to use. The coverslipping film roll should be taken out of the vacuum sealed bag in a dust-free environment and at surrounding temperatures between 18°C to 27°C and humidity levels of 45% to 55%.
- Because of the functional surface structure the amount of Xylene could be reduced by 10%-30%, depending on the type of automatic coverslipper and the material which was used before. For the first usage of this product it is recommended to implement a test with 3-4 drops of Xylene to check the quality of the coverslipping. Depending on the test result the amount of Xylene could be adjusted for getting the optimal coverslipping quality. For further questions please contact your local supplier.
- The covered slides should not be stacked directly on top of each other, otherwise liquid may still come out at the edge during the first 30 minutes after covering.
- If the machine is not used for a longer period of time (several days), it is advisable to remove the coverslipping film roll from the machine and store it in a dust-free place. Alternatively, if the roll remains in the machine for a longer period of time, make sure that the roll is not exposed to an atmosphere containing xylene.

Long Term Storage Conditions After Coverslipping:

- Please store the coverslipped slides in a vertical or horizontal position in suitable containers / slide holders / racks and avoid direct sunlight/UV-light exposure and/or a Xylene or water vapor charged atmosphere.
- Strictly needed long term storage temperatures/relative humidities: 18°C – 25°C / 40%-50% r.H.

Disposal:

- The coverslipping film consists of a plastic material compound which contains mainly cellulose derivate and polyacrylates. The coverslipping film and the Polypropylen (PP) based plastic core have to be disposed according to local, state and federal regulations and laws.
- The product is free from heavy metals, PBB's, PBDE's, DBP, BBP, DEHP and DIBP according to EU-RoHS directives 2011/65/EU Annex II and EU 2015/863. The product is also free from substances of very high concern (SVHC) according to directive EC No 1907/2006/REACH.

Shelf life:

- The product should be used within 18 months after manufacturing (please see the expiry date on the box).

Contacting / Further Information:

- For further information about the product (e.g. SDS, EC Declaration of Conformity) please visit our website: www.islandpolymer.com/pathotape or contact your local supplier or us as the manufacturer:

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