

| Product:      | IsoCoat Zytex®                      | 9 |
|---------------|-------------------------------------|---|
| Trademark:    | SAFE®                               |   |
| REF:          | 435                                 |   |
| Manufacturer: | DACH Schutzbekleidung GmbH හ Co. KG |   |

| Classification:   |                        | CAT III according to the Personal Protective Equipment (PPE) Regulation (EU) 2016/425.<br>Class I of Regulation (EU) 2017/745 on medical devices; UMDNS code: 11-897. |  |  |
|-------------------|------------------------|---|--|--|
| Protection class: | Туре РВ [6]-В          | EN 13034:2005+A1:2009   | Protective clothing against liquid chemicals |  |
|                   |                        | EN 14126:2003+AC:2004   | Protective clothing against infective agents |  |
|                   |                        | EN ISO 13688:2013   | Protective clothing - General requirements   |  |
|                   | CAT3                   | TYP PB [6]<br>EN 13034  | EN14126                                      |  |
| Materials:        | SMS-PP-nonwoven coated | SMS-PP-nonwoven coated with PE-film.  |  |  |





| Product description: | The SAFE® IsoCoat Zytex® is a protective gown that offers maximum all-round protection - back and front! It protects the wearer against blood, viruses, bacteria, contaminated particles and liquid aero according to EN 14126. Also suitable for handling cytostatic drugs.  |                        |                          |                                 |                           |          |
|----------------------|---|------------------------|--------------------------|---------------------------------|---------------------------|----------|
|                      | The gown is maintenance-free due to its single use and thus offers increased safety and protection.<br>Thanks to the signal colour coding, it saves time and effort in everyday life.   |                        |                          |                                 |                           |          |
|                      | <ul> <li>The gown fastens at the neck with a tie. The knitted cuffs are free from natural latex and the tie belt around the waist ensure a perfect fit and excellent coverage, even in combination with protective gloves.</li> <li>The labelling of the packaging fulfills the requirements of EN ISO 15223-1:2021: "Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements".</li> <li>Ideal for applications in wet and extremely demanding environments. Possible fields of application: <ul> <li>Hospitals, care facilities, rescue services</li> <li>Animal welfare</li> <li>Microbiological laboratories</li> <li>Biotechnological industry</li> <li>Sewage work, waste disposal</li> </ul> </li> </ul> |                        |                          |                                 |                           |          |
|                      |   |                        |                          |                                 |                           |          |
|                      |   |                        |                          |                                 | application:              |          |
|                      |   |                        |                          |                                 |                           |          |
| Product performance: | Physical Properties   |                        |                          |                                 |                           |          |
|                      | Property  | Standard               | Unit                     | Result                          | EN-Class/Pass             |          |
|                      | Abrasion<br>resistance  | EN ISO<br>12947-2:2016 | Cycles                   | > 40                            | Pass                      |          |
|                      | Flex cracking<br>resistance / at<br>-30°C   | EN ISO<br>7854:1997    | Cycles                   | >50000 /<br>>4000               | 6                         |          |
|                      | Tear resistance<br>(trapezoidal)  | EN ISO<br>9073-4:1997  | N                        | >20                             | Pass                      |          |
|                      | Tensile<br>strength   | EN ISO<br>13934-1:2013 | N                        | >30                             | Pass                      |          |
|                      | Puncture<br>resistance  | EN 863:1995            | N                        | >5                              | Pass                      |          |
|                      | Seam strength   | EN ISO<br>13935-2:2014 | N                        | >50                             | Pass                      |          |
|                      | Resistance again  | nst penetration b      | y liquid chemicals       | s accordingly EN ISO 6529:2003: |                           |          |
|                      | Chemical  |                        | Repellency-<br>index [%] | EN-Class                        | Penetration-<br>index [%] | EN-Class |
|                      | Sulphuric Acid (3   | 30%)                   | >90                      | 3                               | <1                        | 3        |
|                      | Sodium Hydroxi  | de (10%)               | >90                      | 3                               | <1                        | 3        |





|                       | Resistance against permeation by liquid cytostatic drug accordingly EN ISO 6529:2013:  |  |      |                       |              |
|-----------------------|--|--|------|-----------------------|--------------|
|                       | Chemical   | Breakthrough time (min)                                  |      | EN-Class              |              |
|                       | Cytostatic drug (5mg/ml)   |  |      |                       |              |
|                       | Protective gown is unsuitable for  | for use with Butan-1-ol o-xylene, and organic chemicals. |      |                       | ls.          |
|                       | Protection against infective agents accordingly EN 14126:2003/AC:2004  |  |      |                       |              |
|                       | Test method  | Standard   | Unit | Result                | EN-Class     |
|                       | Resistance to Penetration by<br>Blood-Borne Pathogens - Test<br>method using Phi-X174<br>Bacteriophage   | ISO<br>16604:2004<br>Methode D                           | kPa  | 3,5                   | 3            |
|                       | Resistance to Wet Microbial<br>Penetration   | EN ISO<br>22610:2006                                     | min  | > 75                  | 6            |
|                       | Resistance to Liquid Aerosol<br>Penetration  | ISO<br>22611:2003  | CFU* | Log <sub>10</sub> > 5 | 3            |
|                       | Resistance to Dry Microbial<br>Penetration   | EN ISO<br>22612:2005                                     | CFU* | Log <sub>10</sub> ≤ 1 | 3            |
|                       | *CFU = Colony forming units  | = Colony forming units                                   |      |                       |              |
|                       | The testing has been performed on the garment material. Seams and knitted cuffs have not b tested . Resistance to ignition has not been tested |  |      |                       | ave not been |
| Sizes and Dimensions: | Size   | Length (cm)<br>120                                       |      | Width (cm)            |              |
|                       | Μ  |  |      | 130                   |              |
|                       | L 130  |  |      | 140                   |              |
|                       | XL   | 140  |      | 150                   |              |
| Colour:               | Yellow   |  |      |                       |              |

| Packaging and variants: | Packaging       | Quantity |
|-------------------------|-----------------|----------|
|                         | Bag             | 5 pcs.   |
|                         | Shipping Carton | 50 pcs.  |





| GTIN:  | 435/M   | 4049825007135 |  |
|--|---|---------------|--|
|  | 435/L   | 4049825007142 |  |
|  | 435/XL  | 4049825007159 |  |
| Use:   | For single use only. Read instructions before use.<br>Check for any damages before use and ensure that all seams and closures are intact.<br>Do not use if you see any damage.  |               |  |
| Storage:   | Store dry in original packaging without direct sunlight. (see packaging)<br>If the storage conditions are observed, the product has a storage life of 5 years. (see labeling on the<br>product)   |               |  |
| Environmental<br>sustainability and<br>disposal: | In the case of contaminated products, the type and extent of contamination determines the disposal,<br>and the applicable laws and regulations of the relevant country must be followed.<br>A non-contaminated product can be thermally recycled or disposed of in landfills without releasing toxic<br>substances. |               |  |

