

|                                                                                   |                                                          |                                                               |
|-----------------------------------------------------------------------------------|----------------------------------------------------------|---------------------------------------------------------------|
|  | <b>SAFETY DATA SHEET</b>                                 | Document number<br><b>SDS-2017/HTL- 553-556.01</b>            |
|                                                                                   | <b>Medlance Plus<br/>single-use safety blood lancets</b> | Revision:<br><b>3</b><br>Effective date:<br><b>2020-03-16</b> |
|                                                                                   | <b>Type 553 - 556</b>                                    | Page<br><b>1/3</b>                                            |

**Safety Data Sheet according to Globally Harmonized System of Classification and Labelling of Chemicals (GHS), and Regulation (EC) No 1907/2006 (REACH) – where applicable.**

- SECTION 1: **Medlance Plus safety lancet** is a sterile, single use medical device intended for capillary blood sampling.
- SECTION 2: Hazards identification – no hazards identified
- SECTION 3: Composition/information on ingredients

| <i>Component</i>  | <i>Type</i> | <i>Material</i>                        |
|-------------------|-------------|----------------------------------------|
| Needle            | All         | Stainless steel, silicone coated       |
| Main housing      | All         | Polypropylene or Polyethylene with dye |
| Shield            | All         | Polypropylene with dye                 |
| Rear cap          | All         | Polypropylene with dye                 |
| Drive spring      | All         | Zinc coated steel wire                 |
| Retraction spring | All         | Zinc coated steel wire                 |
| Needle carrier    | All         | Polystyrene with dye                   |
| Shelf box         | All         | Cardboard or polyethylene              |
| Shipper box       | All         | Corrugated cardboard                   |

This product does not contain any natural rubber latex, dry natural rubber, synthetic latex or synthetic rubber that contains natural rubber in its formulation, PVC, Phthalate, Benzol (Benzen), Chloroparaffins, Brominated Additives in any or all of its forms.

No other products containing latex in any or all of its forms are manufactured at the facility where the MediSafe SOLO safety lancets will be manufactured, and no latex substances are used in its production zone.

No natural rubber, dry natural rubber, or any other synthetic derivatives of natural rubber latex are used in: any component of the device, the manufacturing of the device, and any of the device packaging.

As such there is no risk of cross-contamination of the safety lancet products.

Also, operators wear latex-free gloves during the process of assembling and production.

- SECTION 4: First aid measures – not applicable

**Non-controlled document, valid on the day of the printout:**

**03/27/2024 18:32**

|                                                                                   |                                                          |                                                               |
|-----------------------------------------------------------------------------------|----------------------------------------------------------|---------------------------------------------------------------|
|  | <b>SAFETY DATA SHEET</b>                                 | Document number<br><b>SDS-2017/HTL- 553-556.01</b>            |
|                                                                                   | <b>Medlance Plus<br/>single-use safety blood lancets</b> | Revision:<br><b>3</b><br>Effective date:<br><b>2020-03-16</b> |
|                                                                                   | <b>Type 553 - 556</b>                                    | Page<br><b>2/3</b>                                            |

- SECTION 5: Firefighting measures
  - o 5.1. Extinguishing media – water, foam, carbon dioxide, dry chemical powder
  - o 5.2. Special hazards arising from the substance or mixture – no special hazards
  - o 5.3. Advice for firefighters - Respiratory & Eye protection for firefighting personnel
- SECTION 6: Accidental release measure – not applicable
- SECTION 7: Handling and storage - store in clean and dry premises at 5°C - 40°C, humidity up to 85%
- SECTION 8: Exposure controls/personal protection - not applicable
- SECTION 9: Physical and chemical properties – compound device, not a substance
- SECTION 10: Stability and reactivity - device materials are non-reactive and chemically stable in normal conditions, with no specific conditions to avoid nor incompatible materials to contact with
- SECTION 11: Toxicological information – not applicable
- SECTION 12: Ecological information – not applicable
- SECTION 13: Disposal considerations - no special consideration for unused product
  - o 13.1. Waste treatment methods – used devices should be disposed as medical sharp waste in accordance with facility guidelines, national and state regulations
- SECTION 14: Transport information – no special hazard
- SECTION 15: Regulatory information – see point 1.2 – no additional labelling is required
- SECTION 16: Other information - To the best of our knowledge, the information contained herein is accurate. However, neither HTL-Strefa S.A. nor any of its subcontractors or suppliers assumes any liability whatsoever for the accuracy or completeness of the information contained herein.

**Please note that medical devices are considered to be “articles”, therefore not requiring a SDS.**

**Products manufactured or fabricated into an “article” are typically whole units that do not and cannot pose a risk in that they cannot be ingested, inhaled, or absorbed into the body.**

**Non-controlled document, valid on the day of the printout:**

**03/27/2024 18:32**

|                                                                                   |                                                          |                                                               |
|-----------------------------------------------------------------------------------|----------------------------------------------------------|---------------------------------------------------------------|
|  | <b>SAFETY DATA SHEET</b>                                 | Document number<br><b>SDS-2017/HTL- 553-556.01</b>            |
|                                                                                   | <b>Medlance Plus<br/>single-use safety blood lancets</b> | Revision:<br><b>3</b><br>Effective date:<br><b>2020-03-16</b> |
|                                                                                   | <b>Type 553 - 556</b>                                    | Page<br><b>3/3</b>                                            |

## REVISION HISTORY

| No. | CC no.      | Rev. no. | Page | Change description                                                                                                                                                                                                                                                                                                                                                                     | Introduced by | Date       | Effective date: |
|-----|-------------|----------|------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------|------------|-----------------|
| 1.  | CC 154/2017 | 1        | All  | Creation of this document                                                                                                                                                                                                                                                                                                                                                              | M. Szwolgin   | 2017-05-08 | 2017-05-08      |
| 2.  | CC 144/2018 | 2        | All  | Extensions of information in latex-free declaration                                                                                                                                                                                                                                                                                                                                    | M. Szwolgin   | 2018-04-25 | 2018-07-31      |
| 3.  | CC 26/2020  | 3        | All  | Intended use description changed in accordance with product specification; A sentence removed: "Final determination of suitability of any material is the sole responsibility of the user. All materials may present unknown hazards and should be used with caution. Although certain hazards are described herein, we cannot guarantee that these are the only hazards that exist.". | P. Kufel      | 2020-03-10 | 2020-03-16      |

**Non-controlled document, valid on the day of the printout:**

**03/27/2024 18:32**