

# Produktfreigabe / Analysenzertifikat

## Produktfreigabe / Analysenzertifikat

Hiermit bestätigen wir, dass die unten bezeichneten Produkte den technischen Vorgaben und Spezifikationen entsprechen und gemäß den festgelegten Kriterien geprüft und freigegeben worden sind. Die Produkte wurden gemäß den geltenden Vorschriften für Medizinprodukte hergestellt.

## Product Release / Certificate of Analysis

This is to certify that the following products meet all requirements of the appropriate specifications. All products have been inspected according to the relevant test plans and have been released for dispatch and use. The products have been manufactured in accordance with the relevant guidelines for medical devices.

| Art.Nr.<br>Art.No. | Produkt Beschreibung<br>Product description | Chargen Nr.<br>Batch No. | Menge<br>Lot size | Herstelldatum<br>Manufacturing date | Verw. bis:<br>Expiry date: |
|--------------------|---------------------------------------------|--------------------------|-------------------|-------------------------------------|----------------------------|
| 862-1614           | Sysloc needle                               | 210723232                | 1.500             | 2021-07                             | 2026-07                    |

EG-Zertifikat / EC Certificate: G1 17 03 15198 028 (Kanülen, Katheter / Fistula Needles, Catheters) ☐

|                                                                                    |                                                      |                                                               |                                           |                                                                         |
|------------------------------------------------------------------------------------|------------------------------------------------------|---------------------------------------------------------------|-------------------------------------------|-------------------------------------------------------------------------|
| Sterilisationsart /<br>Sterilization Method                                        | <input type="checkbox"/> EO /<br>EO                  | <input checked="" type="checkbox"/> Strahlen /<br>Irradiation | <input type="checkbox"/> Dampf /<br>Steam | <input type="checkbox"/> Unsterile – Produkte<br>Non – sterile Products |
| Sterilisationsprüfung /<br>Sterility Results                                       | <input checked="" type="checkbox"/> i.O. /<br>passed | <input type="checkbox"/> n.i.O. /<br>not passed               |                                           | <input type="checkbox"/> Nicht zutreffend<br>Not applicable             |
| LAL-Test /<br>LAL- Test                                                            | <input type="checkbox"/> i.O. /<br>passed            | <input type="checkbox"/> n.i.O. /<br>not passed               |                                           | <input checked="" type="checkbox"/> Nicht zutreffend<br>Not applicable  |
| Pyrogenprüfung /<br>Pyrogen Results                                                | <input checked="" type="checkbox"/> i.O. /<br>passed | <input type="checkbox"/> n.i.O. /<br>not passed               |                                           | <input type="checkbox"/> Nicht zutreffend<br>Not applicable             |
| Technische Daten –<br>Leistungswerte/<br>Technical Data -<br>Performance Results - | <input checked="" type="checkbox"/> i.O. /<br>passed | <input type="checkbox"/> n.i.O. /<br>not passed               |                                           | <input type="checkbox"/> Nicht zutreffend<br>Not applicable             |
| Analyse Daten /<br>Chem. Analysis results                                          | <input type="checkbox"/> i.O. /<br>passed            | <input type="checkbox"/> n.i.O. /<br>not passed               |                                           | <input checked="" type="checkbox"/> Nicht zutreffend<br>Not applicable  |

Datum / Date 18.01.2022

Unterschrift / Signature ia O. Jankel

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