



Declaration of Conformity according to Medical Device Regulation MDR 2017/745 Annex IV

We hereby declare that this EU Declaration of Conformity is issued under the sole responsibility of the manufacturer and the below mentioned products meet the provisions of the EU Regulation above. All supporting documentation is retained on the premises of the manufacturer and the Notified Body.


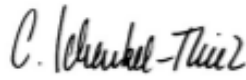
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|---|--|
| Products | C-Plast Polymer Weiss C-Plast Polymer F.34 C-Plast Monomer |
| Project Number(s) / Change Number(s) | 63 13 90 |
| Basic-UDI-DI | 763081341XTRAY0018Z |

| Legal manufacturer | |
|--|---|
|  | Candulor AG Boulevard Lilienthal 8 8152 Glattpark/Schweiz www.candulor.com |

| EU Declaration of Conformity Information | |
|---|--|
| SRN | CH-MF-000015795 |
| Intended Purpose | Tray material |
| EU Risk Classification (MDR Annex VIII) | Medical Device Class I  |
| Conformity Assessment Procedure (MDR Annex IX) | Quality Management System |
| MDR Certificate No. | G20 090341 0017 Rev. 00 |
| Valid until | 2025-05-25 |

Attachment to EU Declaration of Conformity

| Article No. | Description | MDR Classification (EU) | Rule MDR (EU) |
|-------------|-----------------------------|-------------------------|---------------|
| 672719 | C-Plast Polymer 500g, weiss | Class I | 5, bullet 1 |
| 672722 | C-Plast Polymer 500g, F34 | Class I | 5, bullet 1 |
| 674272 | C-Plast Monomer 500ml | Class I | 5, bullet 1 |

| Document Control | | | |
|--|----------------|---------------|---|
| Name | Place of issue | Date of issue | Signature |
| Approver (PRRC): Alexander Schwaszta | Glattpark, CH | 2024-05-22 |  |
| Approver (Managing Director): Claudia Schenkel-Thiel | Glattpark, CH | 2024-05-22 |  |

| Revision History | | | |
|------------------|------------|---------------|--|
| Version | Date | Author | Remark |
| 1.0 | 2020-07-20 | Miriam Stange | First MDR Version |
| 2.0 | 2021-12-02 | Miriam Stange | Correction of validity date |
| 3.0 | 2024-05-13 | Miriam Stange | Removal of Basic UDI-DI HIBC / use of Basic UDI-DI GS1 Removal of DE SRN Correction of validity date |