

**MELAcontrol Helix**  
**Set incl. 250 indicator strips**

Art.-Nr.: 01082

Kunde	MELAG Medizintechnik GmbH & Co. KG
Customer	Geneststraße 6-10 D-10829 Berlin

**1. Anwendungsgebiet / Application area**

The MELAcontrol Helix is used in conjunction with the indicator strip to verify that the sterilization process in steam sterilizers has been safely completed.

**2. Materialspezifikation / Material specification**

After printing and before cutting, the indicators must undergo conditioning at  $25 \pm 5$  °C and  $40 \pm 10\%$  RH for at least 21 days, with 1,000 sheets per stack. The indicators must be stored as stacked printed sheets, protected from dust and light (paper wrapping). The expiration date of the indicators must be at least 36 months upon delivery. Indicators must be supplied according to the following specifications:

- Indicator substance 3MFID0016 with catalyst 15% (Indicator Systems)
- Indicator substrates
  - Cardboard, satin finish – 170 g/m<sup>2</sup> (Article No.: 10170 VPF)
  - Kraft paper NSA1100-473/-477 white (VPF)
  - Permanent-958 (VPF)

The test device (PCD) must be supplied in accordance with the final version dated 04.11.2024 with a 1.5 m long Teflon hose. The Teflon hose must protrude 5 mm from the test device, below the capsule.

**3. Chargenkennzeichnung / Batch identification**

For traceability, each set must be marked with a batch number (LOT) on the packaging. It must be ensured that the batch number is clearly visible (size, shape, etc.).

**4. Anlieferbedingungen / Delivery conditions**

The delivery must be delivered in pure batches, with only two batch numbers being allowed per delivery. If the delivery includes two batches, this must be done in separate packaging, separating layers in one packaging are not permitted.

The individual packaging is done in a box that is completely labeled according to the template. One unit contains the following products:

- 1 x MELAcontrol Helix
- 1 x card with a color scale
- 250 x indicator strips packed in a resealable PE bag

**5. Lieferdokumentation / Delivery documentation**

Delivery note with the following information:

- MELAG article number and article description,
- the batch numbers with their respective quantities,
- the expiry date of the indicators

**6. Konformität / Conformity**

Current certification/declaration that the product conforms to EN ISO 11140-6 must be given.

**7. Prüfung / Inspection**

A random sample inspection of incoming goods must be carried out by the person responsible for the product.