# CERTIFICATE

## EN ISO 13485:2016

DEKRA Certification GmbH hereby certifies that the organization

### Kunststoff Helmbrechts AG

#### Scope of certification:

Injection molding, painting, assembly and distribution of plastic components for medical application Assembling of single use endoscopes according to customer contract

#### **Certified location:**

Pressecker Straße 39, 95233 Helmbrechts, Germany (further locations see annex)

has established and maintains a quality management system according to the above mentioned standard. The conformity was adduced with audit report no. 51463-Z3-00.

Certificate registration no .: 51463-14-03 EN Validity of previous certificate: 2023-03-13

Certificate valid from: Certificate valid to:

2023-03-14 2026-03-13

DEKRA

DEKRA Certification GmbH, Stuttgart, 2023-03-13

DAkkS Deutsche Akkreditierungsstelle D-ZM-16029-08-00

DEKRA Certification GmbH \* Handwerkstraße 15 \* D-70565 Stuttgart \* www.dekra.com/medical-devices

## Annex to the Certificate No. 51463-14-03

valid from 2023-03-14 to 2026-03-13

The following locations/companies belong to the certificate above:

	Headquarters		Scope of certification
	Kunststoff Helmbrechts AG	Pressecker Straße 39 95233 Helmbrechts Germany	see page 1
	at the following locations/at the companies at the following locations		Scopes of certification
1.		Fliegerweg 2 95233 Helmbrechts Germany	Painting, assembly and distribution of plastic components for medical application



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