
PCN Number: 13485_01/2023

Title: **Change production, distribution and service of MED ace series from quality management system DIN EN ISO 13485:2016 to DIN EN ISO 9001:2015**

Product Family: MED ace series

Release date: November 30, 2023

Contact: Basler Support

Type of Change:

<input type="checkbox"/> Miscellaneous	<input type="checkbox"/> Firmware	<input checked="" type="checkbox"/> Certificates / Conformities
<input type="checkbox"/> Product design	<input checked="" type="checkbox"/> Process	<input checked="" type="checkbox"/> Decision Matrix Product Changes

Reason for Change

In march 2018 Basler introduced the Basler MED ace series with originally 12 camera models with USB3 and GigE Interface. Over the last 6 years we expanded the feature set continuously and increased the range of MED ace series to 22 camera models.

When introducing this camera series one aspect was the production, distribution and service under DIN EN ISO 13485:2016 and a second aspect was to provide special features to these special market requirements. With the introduction of the DIN EN ISO 13485:2016 quality management system, we saw the advantage of the reduced effort involved in integrating the camera and subsequent certification of customer systems in accordance with DIN EN ISO 13485:2016.

As Basler we want to offer products to our customers which have the best price performance ratio, are reliable and easy to integrate.

When we analyzed the feedback from our customers, we came to the conclusion that production, distribution and service in accordance with DIN EN ISO 13485:2016 did not bring as much benefit to our customers as originally expected.

To keep these products in a good price performance ratio Basler decided to not produce, distribute and service these cameras under DIN EN ISO 13485:2016 any longer.

Change Description

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PRODUCT CHANGE NOTIFICATION (PCN)

Basler will start to produce, distribute and service the MED ace series according to DIN EN ISO 9001:2015 in March 2024. For traceability of this change the cameras will receive a new revision which is visible on the packaging and the camera itself.

There is no change on the cameras functionality this means no change on form, fit, function of the cameras.

The product series will remain as they are with special MED feature set:

- Dust protection +
- Brilliant image
- Perfect color
- Low light imaging
- Industrial excellence
- High speed

Please check our Feature Check List Medical & Life Sciences for detailed information.

With the change of the quality management system we will not comply with special regulation differences between DIN EN ISO 9001:2015 and DIN EN ISO 13485:2016 any longer.

The following table shows the MED ace characteristics after this change:

MED FW feature set	✓
MED Dust protection+ feature	✓
Frozen FW / Frozen HW	✗
Traceability	✗
Decision matrix for change management	✗
Validation of production processes	✗

MED FW feature set: will remain unchanged.

MED Dust protection+ feature: will remain unchanged.

Frozen HW/ Frozen FW: will not be a feature for by default anymore. This feature can be requested as customization as for all DIN EN ISO 9001:2015 cameras. For more information please see this [Link](#).

Traceability: cannot be guaranteed 100% to the lowest level of components anymore. But we still have the good traceability of our DIN EN ISO 9001:2015 processes.

Decision matrix for change management: The special MED decision matrix will not be used anymore. But will still publish product change notifications for changes which affect form, fit or function. These PCNs will be sent to you via newsletter once you have registered and will be uploaded on our website.

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PRODUCT CHANGE NOTIFICATION (PCN)

Validation of production processes: Will not be validated according to DIN EN ISO 13485:2016 anymore, but will be validated according to DIN EN ISO 9001:2015.

You have the possibility to order the old revision of each camera listed below produced, distributed and serviced under DIN EN ISO 13485:2016 until **31.01.2024**. Please note that the delivery date must be before **22.03.2024**.

Due to unexpected high demand the possibility to produce under DIN EN ISO 13485:2016 can be limited and the period might end earlier at short notice and no more orders can be placed. Therefore, we kindly ask you to order your amount in time.

We understand the challenges this change may causes and will do our best to guide our customers along the way finding appropriate solution. Please contact your sales representative.

Any supply will be subject to Basler AG's capacity and resource constraints as well as to timely and contractual supply by pre-suppliers.

Affected models and expected first production / shipping date

Model	Part Number	New revision	Production Date
Basler MED ace 2.3 MP 164 mono	107495	07	March 2024
Basler MED ace 2.3 MP 164 color	107496	07	March 2024
Basler MED ae 5.1 MP 75 mono	107497	08	March 2024
Basler MED ace 5.1 MP 75 color	107498	08	March 2024
Basler MED ace 5.3 MP 20 mono	107499	07	March 2024
Basler MED ace 5.3 MP 20 color	107500	07	March 2024
Basler MED ace 2.3 MP 41 color	107610	07	March 2024
Basler MED ace 2.3 MP 41 mono	107611	07	March 2024
Basler MED ace 5.1 MP 35 color	107612	08	March 2024
Basler MED ace 5.1 MP 35 mono	107613	08	March 2024
Basler MED ace 6.4 MP 59 mono	108142	03	March 2024
Basler MED ace 6.4 MP 59 color	108143	03	March 2024

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PRODUCT CHANGE NOTIFICATION (PCN)

Model	Part Number	New revision	Production Date
Basler MED ace 20.0 MP 17 mono	108144	03	March 2024
Basler MED ace 20.0 MP 17 color	108145	03	March 2024
Basler MED ace 8.9 MP 42 mono	107812	04	March 2024
Basler MED ace 8.9 MP 42 color	107813	04	March 2024
Basler MED ace 8.9 MP 32 mono	107814	04	March 2024
Basler MED ace 8.9 MP 32 color	107815	04	March 2024
Basler MED ace 12.3 MP 30 mono	107816	04	March 2024
Basler MED ace 12.3 MP 30 color	107817	04	March 2024
Basler MED ace 12.3 MP 23 mono	107818	04	March 2024
Basler MED ace 12.3 MP 23 color	107819	04	March 2024

Customized cameras based on the same product models are effected as well. These customers receive a special PCN.

Additional Information

There is no claim to exchange or update the customers stock or the delivered goods due to the PCN. Also there is no claim to receive the old revision after change.

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