CERTIFICATE OF ANALYSIS (COA) – SYKONAHALER

Supplier: **Mematec Products GmbH**
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Customer:	**Unternehmen**	**Date:**	xx.xx.xxxx
Customer Order No.:	(Nummer von Bestellung)	**Production order No.:**	(interne Produktionsnr.)
Product Name:	SykonaHaler-Part	**Article Number:**	MC-P083-001
Order Quantity:	(Anzahl der Bestellung)	**Mematec Lot No.:**	(Batchnumber)
Manufacturing Date:	xx.xx.xxxx – xx.xx.xxxx	**Batch size:**	(Batchsize)
Date of Quality-Check:	xx.xx.xxxx	**Number of selected parts for QA-Check:**	(According to VA3.08-06 Überwachung und Messung von Produkten)
Date of shipment:	xx.xx.xxxx	**Recommended shelf life:**	xx.xx.xxxx (5 years)

Remark: The standard risk classification is based on the CPK values achieved. If the CPK value is >1.67, the risk is minor. If the CPK value is between 1.33 and 1.67, the risk is major. If the CPK value is less than 1.33, the risk is critical. Table 1 shows the related AQL.

Table 1: AQL and test level

Risk level	assumed AQL	Test Level
Risk low / minor	0,65	S2
Risk medium / major	0,10	S2
Risk high / critical	0,025	S2

Furthermore, mematec can adjust the AQL based on customers risk classification. In the table 2 the customers AQL is shown. In standard mematec cases we take the same AQL as it is been taken for the internal QAP checks (According to VA3.08-06 Überwachung und Messung von Produkten und SOP 5.86-02_ Mora Qualitätskontrolle). Shown in the Result column. First number shows the selected samples, second number the failed number.

Selected AQL Procedure:

☐ **AQL and test level according to mematec standard procedure (table 1)**
☐ **AQL and test level according to customer target (AQL value shown in table 2)**
☐ **S2** ☐ **S3** ☐ **S4**

Table 2: Performed tests

	Criteria to test	Test methods	Requirements	Acceptance Criteria / AQL	Result Total-No./ No. of failed samples	Complies Yes/No
QAP_1	Number of parts ordered	Counting parts	The number of parts produced corresponds to the number ordered (Number of parts per carton)	-	-	
QAP_2	Order content	Visual inspection	The parts delivered correspond to the order (Delivery note vs order)	-	-	
QAP_3	Drawing version	Visual inspection	The current drawing version has been selected.	-	-	
QAP_4	Delivery date	Visual inspection	Delivery date adhered to by the supplier	-	-	
QAP_5	Batch number	Check the number	Batch number is entered in the system	-	-	
QAP_6	Color	Visual inspection	The supplied colour corresponds to the order for customer-specific components (OuterCase)	-	20/ 0	
QAP_7	CKP	Visual inspection	The CPK analysis was supplied.	-	-	
QAP_8	Label	Visual inspection	Shipping label of supplier is according to QSV and affixed to each box.	100% of cartons	-	
QAP_9	Shipping documents	Visual inspection	Shipping documents are available. (delivery note, customs documents if applicable...)	-	-	
QAP_10	CPK 1,67	Visual inspection	The CPK values are 1.67 or greater	0,65	__ / 0	
QAP_11	CPK	measurement	The supplier's CPK values are randomly checked by our own measurements and are plausible.	-	2/ 0	
QAP_12	Weight	measurement	The weight of the tested individual parts is within tolerance. < 2g: ± 0,05 g 2 - 5 g: ± 0,2 g 5 g - 19 g: ± 0,4 g 20 g -50 g: ± 0,6 g	-	10/ 0	
QAP_13	Damage	Visual inspection	The parts show no damage and are in a clean condition.	0,65	__ / 0	
QAP_14	Dust / Dirt	Visual inspection	There are no visual traces of release agents, oils or greases on the parts produced.	0,65	__ / 0	
QAP_15	Surface	Visual inspection	The surface is smooth and burr free, the roughness is according to the specification (comparison with older deliveries)	0,65	__ / 0	
QAP_16	Engraving	Visual inspection	Any engravings are neatly formed	0,65	__ / 0	
QAP_17	Material	Visual inspection	The parts are not soiled by other material (visible areas of different colors)	0,65	__ / 0	
QAP_18	Color	Visual inspection	Visual verification of color fastness only for color white with color plates (guarantee of color reproducibility)	0,65	__ / 0	
QAP_19	Numbers	Visual inspection	TH5: The numbers are fully visible in gauge KA004	0,65	__ / 0	
QAP_20	Grid	Visual inspection	TH4: The cross in the respiratory pathway is completely injected and not oversprayed.	0,1	__ / 0	
QAP_21	Indexing	Visual inspection	The assembled device can be indexed 63 times without blister strips. The numbers in the counter reading at the beginning is "hole" and at the end "0"	-	4/ 0	
QAP_22	Counter	Visual inspection	The assembled device can be indexed 62 times with blister strips. The meter reading at the beginning is "triangle" and at the end "0" (only if a blister strip mematec is provided by the customer)	-	1/ 0	
QAP_23	IFR	Dusa	The respiratory data measured at the test pocket are within tolerance. (80l/min +15% at 4 kPa) (measured with blister strips)	-	1/ 0	
QAP_24	Drop test	Visual inspection	The device passes the drop test. (SOP_5.86-02_Mora_Qualitätskontrolle: QAP_10 Droptest)	-	5/ 0	
25	Packaging	Visual inspection	• Device is packed in 2x PE bag according specification	100% of cartons	-	
26	Quantity	Visual	• Device is packed in PE bag according	100% of cartons	-	

		inspection	specification SOP_5.86-03, quantity			
27	Damage	Visual inspection	• Completeness of components (functionality completely compromised) • Nothing broken/damaged, functional components (functionality completely comprised) • No dust, fibers and dirt • No small deformations / cracks	0,65	20/ 0	
28	Identification	Visual inspection	• PE bags are packed in cartons. Cartons are labeled according to the specification	100% control	-	
29	Delivery	Visual inspection	• Completeness of packing, cartons packed on Euro Pallets. Number of cartons according to specification (SOP_5.86-03)	100% control	-	

Conformity Declaration

The manufacturing batch documentation and analytical documentation was reviewed and found in accordance with ISO 13485 and Matematec quality management procedures. The part was manufactured with the materials described in the CoC and according to Matematec procedures.

Notes:

CoA		
Location:	Matematec Products GmbH August-Müller-Straße 24 71691 Freiberg am Neckar	Matematec Products GmbH Carl-Benz-Straße 10 74354 Besigheim

Stemp

	Name	Function	Date	Signature
Performed	Magdalena Dawidowska	Head of production		
Approved	Markus Mezger	CEO and Owner		

RELEASE OF DOCUMENT

Created	Verified	Released
by: Stefan Verbakel	by: Magdalena Dawidowska	by: Markus Metzger
Head of Engineering	Head of production	CEO
Date: 09.07.2024	Date: 09.07.2024	Date: 09.07.2024
Stefan Verbakel Signature	Dawidowska Signature	Signature

VERSION HISTORY

Version	Date	Author	Description
1.0	21.02.2023	Stefan Verbakel	COA with reworked tests as guided document
2.0	05.02.2024	Stefan Verbakel	New layout to be similar with Mora COA
3.0	09.07.2024	Stefan Verbakel	Part weight tolerances added