



Fraunhofer

**TESTED[®]
DEVICE**

hawo GmbH
hm 4000 DC-VI

Report No. HA 2104-1228

DUPLICATE

Statement of
Qualification

Single product
Hygienic Design

Statement of Qualification · Single product

Customer	hawo GmbH Obere Au 2-4 74847 Obrigheim Germany
Component tested	
Category:	Working Place and Operator
Subcategory:	Work Equipment
Product name:	sealing machine hm 4000 DC-VI (manufacturing date: 3/18/2021; color: V2A stainless steel; article number: 0.617.344; serial number: 493143; weight: 19 kg)

Assessment of conformity to GMP regulations as well as to EHEDG conception and design recommendations

Standards/Guidelines:	EU GMP Annex 1; EHEDG Doc. 8; DIN EN 1672-2; ISO 14159 The norms stated generally refer to the version valid at the time of the tests.
Assessment criteria:	<ul style="list-style-type: none">Materials utilizedMaterial pairingsInstalled componentsGeometries of components usedJoining methodsDetailed constructional solutionsManufacturing processesSurface coatings/coating systems <p>The suitability of the operating utility for use in a GMP-conform manufacturing environment is ascertained on the basis of the assessment of these criteria with the aid of expert knowledge. The assessment focuses mainly on the avoidance of contamination as well as on the ability to clean and disinfect the operating utility.</p>

Test result / Classification


The sealing machine hm 4000 DC-VI is principally suitable for use in hygienic areas up to the following GMP Class according to EU GMP Annex 1:

Suitability
up to GMP Class C

However, this recommendation only pertains to the operating utility when in a resting state. An overall assessment of the sealing machine hm 4000 DC-VI can only be made after its installation in the production line.

The measuring devices used for the qualification tests are calibrated at regular intervals; their results can be traced back to national and international standards. In cases where no national standards exist, the test procedure implemented complies with the technical regulations and norms applicable at the time of the test. The relevant documentation can be viewed on request at any time.

Detailed information and parameters of the test environment can be found in the Fraunhofer IPA test report.

Fraunhofer Institute for Manufacturing Engineering and Automation IPA	HA 2104-1228 Report No. first document	Stuttgart, May 27, 2021 Place, date of first document issued
Department of Ultraclean Technology and Micromanufacturing	-- Report No. current document	-- Place, current date
Nobelstrasse 12 70569 Stuttgart Germany	on behalf of Dr.-Ing. Frank Bürger, Project Manager Fraunhofer IPA	

This document only applies to the named product in its original state and is valid for a period of 5 years from the date the first document was issued. The document can be verified under www.tested-device.com.