valid until: March 1, 2029

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TESTED®
DEVICE

hawo GmbH
HM 5000 PRINTPAK MED
Report No. HA 2401-1488

Statement of
Qualification

Single product
Hygienic Design

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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: HM 5000 DC-VI PRINTPAK MED SEALING EQUIPMENT + INKJET
consisting of:
- HM 5000 C INKJET LEIBINGER IQJET (manufacturing date: 5/2023; type: IQJET; article number: 99-007000-70-0006; serial number: 5IQ-000378)
- HM 5000 DC-VI PRINTPAK MED SEALING EQUIPMENT (manufacturing date: 4/2023; material: V2A stainless steel; weight: 22 kg; type: HM 5000 DC-VI Sealing Equipment V1.01.01; article number: 1.617.029; serial number: 545579)

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:
- Materials utilized
- Material pairings
- Installed components
- Geometries of components used
- Joining methods
- Detailed constructional solutions
- Manufacturing processes
- Surface coatings/coating systems

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.

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Test result / Classification

The system HM 5000 DC-VI PRINTPAK MED SEALING EQUIPMENT + INKJET is principally suitable for use in hygienic areas up to the following GMP Classes according to EU GMP Annex 1:

System component	Suitability
HM 5000 C INKJET	up to GMP-Klasse D
HM 5000 DC-VI PRINTPAK MED	up to GMP-Klasse C
Overall result	**up to GMP Class D**

However, this recommendation only pertains to the operating utility when in a resting state. An overall assessment can only be made after its installation in the production environment.

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

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-- — Place, current date

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**.