ZERTIFIKAT ◆ CERTIFICATE ◆ 認証書 ◆ ΈΡΤΙΤΤΑΤ ◆ CERTIFICADO ◆ CERTIFICAT

Industrie Service

Chamberlain Machine, Inc.

17 Huntington Lane

Walpole, NH 03608

has been audited and approved on the basis of the requirements of the German

AD2000-Merkblatt HP0, Sections 3.2, 3.5 and 4

All relevant requirements have been met. Among others, the organisation fulfils the following:

- Facility and equipment permitting proper manufacturing, testing and inspection of pressure equipment in acc. with the above referenced regulations and codes
- A quality assurance program, which guarantees that manufacturing, testing and inspection of products are carried out in accordance with the requirements
- Component supervisory and inspection personnel.

This certificate is non-transferable and valid through October 2017.

Certificate Number:
USA/15/09/262/001

TÜV SÜD Industrie Service GmbH

Dipl. –Ing. (Univ.) Dirk Schroeter

Schaumberg, IL, October 7, 2015

Notified Body No.: 0036

TÜV SÜD
Industrie Service GmbH
Westendstrasse 199
D-80686 München

Test Laboratory for Pressure Equipment: Industry Service,
TÜV SÜD America, Inc.
10 Centennial Drive
Peabody, MA 01960

Member of
CONFÉDERATION EUROPÉEN
CEOC
D'ORGANISMES DE CONTROLE

Industrie Service	**Factory Inspection Report**	Industrie Service
		Page 1 of 5

Company / Client:	Chamberlain Machine, Inc.			
Street/ P. O. Box:	17 Huntington Ln.			
Place:	Walpole, NH 03608			
Order number:	72110183	Certificate No.	USA/15/09/262/001	
Lead Auditor/Inspector:	--	Auditor:	Dirk Schroeter	
Auditee's Representative:	Mark Messer- Quality Assurance Manager			
Scope of Application:	Manufacturing of pressure equipment parts for Philips Medical			
Remark:	Philips Medical Supplier			
Date of Audit:	September 28, 2045			
Standard:	☐ ISO 9001	☐ ISO 9002	☐ ISO 9003	☐ ISO 14001
Audit type:	☐ Pre-Audit		☐ 1. Follow-up	
	☐ Certification Audit		☐ 2. Follow-up	
	☐ Re-Audit		☑ Re-certification Audit	
	☐ Expansion Audit		☒ **AD2000 Merkblatt HP0, Sections 3.2, 3.5 and 4**	

1 Objective:

Recertification plant facility audit per AD2000-HP0 Sections 3.2, 3.5, and 4. The previous re-certification audit was in 2013.

2 Contract:

Chamberlain Machine, Inc. has contracted TÜV SÜD Industrie Service GmbH through its subsidiary TÜV SÜD America, Inc. to audit and certify its manufacturing facility according to the applicable requirements of the AD2000-HP0 standard for the machining of pressure equipment parts which will be used by Philips Medical. The Scope of this approval includes the manufacture of the following parts:

(for a list of parts, see Attachment 2 of the HP0 Questionnaire)

3 Company Information:

Chamberlain Machine, Inc. has been in business since 1943 and provides various machining and fabrication services for several industries, including the machining of parts for Philips Medical. The company currently employs 47 employees, with 35 working in production.

4 Performance of the Audit and detailed Evaluation Results:

Meetings were held with Mark Messer, as well as with personnel responsible for production, engineering, inspection, and quality control.

The TÜV SÜD Industrie Service inspector / auditor assessed and reviewed all aspects of manufacturing.

Chamberlain performs an inspection of incoming materials to verify that the material, material certificates, markings, and dimensions correspond to their Purchase Order and applicable standards. It is noted on the Purchase order if items require a transfer of markings, and these items are immediately routed to the works inspector as defined in the works inspector list (Attachment 3 to the HP0 Questionnaire), who will immediately transfer the markings onto the parts along with a job number. Parts remain traceable through all processes through this job number. Prior shipping, a final inspection will take place to ensure that all markings and dimensional requirements specified by Philips Medical Drawings as well as applicable standards are met and a Stamping Transfer Certificate is in place.

Any subsequent test on the completed pressure equipment will be performed under the responsibility of Philips Medical.

The TÜV SÜD America inspector assessed and reviewed all aspects of manufacturing the planned pressure equipment parts.
Chamberlain is adequately equipped with machines, tools, and other devices necessary for production and inspection of pressure equipment parts as specified in the listed drawings above (see Attachement 2 of the HP0 Questionnaire). The equipment is state of the art, in generally good condition, and seemingly well maintained and calibrated (where applicable).

The requirements of AD2000-HP0 are fulfilled.

SUBJECT	DESCRIPTION
Quality Assurance System / Quality Planning	The auditor determined that Chamberlain meets all quality aspects as required by the code. The quality assurance system seems suitable and is effectively implemented. No findings were observed. Chamberlain is certified according to ISO 9001:2008, Cert. No: US 10/74615
Contract Review	The auditor reviewed several purchase orders against specific product requirements. No findings were observed.
Document and Data Control	All documents are available at the workplaces. The system is adequately controlled and maintained. If procedures or work instructions and forms need to be changed, selected individuals have access authorization, in order to revise. No findings were observed.

Product ID & Traceability	The auditor determined that products and test samples are suitably and sufficiently identified and traceable during the entire manufacturing process. Products located in all areas of concern for this audit were properly identified and traceable. It was found that no procedure existed for performing the transfer of markings as required by the Transfer Stamping agreement. See attached action list with Corrective Action.
Process Control	The auditor followed the production flow and came to the conclusion that all process tasks are seemingly well controlled and that requirements are observed by all personnel. No findings were observed.
Inspection and Testing	Inspection equipment used is state of the art. The staff is properly trained and sufficiently knowledgeable about the applicable inspection procedures and requirements. Chamberlain performs dimensional inspections together with a final inspection. No findings were observed.
Control of Inspection Measurement and Test Equipment	Inspection equipment is properly calibrated and labeled, indicating due date, date of last calibration and equipment serial number. The overall control of measurement and test equipment is suitably performed. No findings were observed.
Control of Non-conforming Product	Non-conforming product will be adequately identified and segregated. Documents and records are traceable and the inspection results are suitably outlined. No findings were observed.
Corrective and Preventive Action	This seems, in general, adequately addressed and implemented. No findings were observed.
Handling, Storage, Packaging, Preservation and Delivery	This seems adequately addressed and implemented. No findings were observed.
Quality Records	Procedure QPF 01.3, Rev. D specifies a max. record retention of 5 years. Quality records should be kept 10 years; this is a requirement for subcontractors of PED (97/23/EC) certified companies such as Philips Medical. See attached action list with Corrective Action.

Training of Employees	This seems adequately addressed and implemented. No findings were observed.

5 Materials

Chamberlain provides machined pressure equipment parts to Philips Medical out of stainless steel according to ASME SA-240 or SA-479 Grade 304/304L.

It is not intended to restrict the production exclusively to above listed material. However, if other materials are chosen, their suitability needs to be proven to the TÜV SÜD inspector prior to production.

Chamberlain purchases material from AD-2000 W0 approved material manufacturers, according to customer specifications.

6 Obligations and Restrictions

Chamberlain is obligated to inform the TÜV SÜD inspector of any changes regarding responsible personnel and changes with respect to manufacturing methods and procedures that may affect the quality and safety of the pressure equipment parts. Such changes may require re-evaluation by TÜV SÜD.

In justified cases and at any time during production, TÜV SÜD inspectors are entitled to check that the requirements Chamberlain is obligated to meet, are still being met.
Chamberlain does not employ any heat treating or welding procedure(s) in the production for these parts. This approval excludes heat treatment and welding on pressure boundary parts.

7 Final Conclusion

The TÜV SÜD America inspector hereby acknowledges that Chamberlain has:

- facility and equipment which permit state of the art product manufacturing and inspection of dimensional control, in accordance with above mentioned requirements (AD2000-HP0),
- a quality system which guarantees proper material handling, meeting the requirements of applicable rules and regulations,
- competent supervisory and inspection personnel.
- The Transfer Stamping agreement has been revised and reissued.

TÜV SÜD Industrie Service GmbH confirms that

Chamberlain Machine, Inc
17 Huntington Ln.
Walpole, NH

meets applicable requirements (AD2000-HP0) as a manufacturer of pressure equipment parts for Philips Medical.

8 Withdrawal of Approval

Should the above explicit obligations not be met at any time during the designated validity of this approval, a TÜV SÜD Industrie Service inspector / auditor may, by documenting his/her observations in writing, recommend and affect the suspension and/or cancellation of this approval.

This approval shall remain valid until April 2017. It may be extended upon request.

Schaumberg, IL, October 7, 2015

The Auditor

Dipl.-Ing. (Univ.) Dirk Schroeter
TÜV SÜD America, Inc.

TÜV SÜD Industrie Service GmbH

Trainee

Brandon Corey
TÜV SÜD America, Inc.