

IN-HOUSE INSPECTION SERVICE

Approval of In-house Inspection Service according to Swedish Civil Contingencies Agency's regulation MSBFS 2011:3 (2010/35/EU) and ADR 1.8.7.6 "Surveillance of the applicant's In-house inspection service".

CERTIFICATE NO.: T224-B2, Rev. 18

This Certificate consists of 2 pages

KIWA INSPECTA AB

hereby approve that the Manufacturer

GCE s.r.o., 583 01 Chotěboř, Czech Republic

for pressure equipment assessed under

EU Type-Examination Certificate No: **See Enclosure 1 to T224-B2 Rev. 18**

have the right to perform In-house inspection service according to the attached specification regarding product type/types and associated audits according to MSBFS 2011:3 (2010/35/EU) and ADR 1.8.7.6 at the following production facilities:

GCE s.r.o. 583 01 Chotěboř, Czech Republic

The following equipment/products are concerned:

See Enclosure 1 to T224-B2 Rev. 18

For approval, the following conditions apply:

- The arrangement of the in-house inspection service and documentation, cannot be altered with respect to the documents that have been a basis for the application, without written approval from Kiwa Inspecta AB.
- Periodic audits shall be performed by Kiwa Inspecta AB with a minimum of two audits in a 12 month period.
- Responsible for the in-house inspection service is (name and title): Vlastimil Strnad, QM Manager.

This certificate is valid until: 2021-12-19


Under the condition that above given terms are fulfilled and that the regulations in MSBFS 2011:3 (2010/35/EU) have been taken into account and that the regulations in the same are not changed.

The manufacturer is allowed to affix the "π" mark followed by the Notified Body number 0409 (Kiwa Inspecta AB) to the approved equipment described in the chapter 3 of the TPED Directive (2010/35/EU).

MALMÖ, 2020-08-17

Kiwa Inspecta AB

Notified Body No.: 0409



Olof Pedersen

Senior Design Review Engineer



Notice: The certificate is subject to terms and conditions, if any, overleaf. Any significant changes in design or construction of the product, the quality system or amendments to the MSBFS 2011:3 (Directive 2010/35/EU) or Standards referenced above may render this certificate invalid. The product liability rests with the manufacturer or his representative in accordance with the MSBFS 2011:3 (Directive 2010/35/EU), as amended..

IN-HOUSE INSPECTION SERVICE

CERTIFICATE NO.: T224-B2, Rev. 18

EXAMINED TECHNICAL DOCUMENTATION

See Enclosure 2 to T224-B2 Rev. 18.

LIMITATIONS

Periodic audits must be carried out by Kiwa Inspecta AB or by a Kiwa Inspecta AB appointed representative:
Mr Antonín Otoupal, DNV GL Business Assurance Czech Republic s.r.o.

TESTS CARRIED OUT

See Enclosure 2 to T224-B2 Rev. 18.

MALMÖ, 2020-08-17

Kiwa Inspecta AB

A blue ink signature of Olof Pedersen, with the "Kiwa Inspecta" logo in blue text to its right.

Olof Pedersen
Senior Design Review Engineer

Enclosure 1 to T224-B2 Rev 18

VALIDITY
TPED Valves

Type	Certificate No	Rev No
Shut off Valves for Cylinder Bundles with rotating design and with non-rotating design	Inspecta 12-466227-00	2
Cylinder Valves with rotating design	Inspecta 12-466227-01	1
Cylinder Valves with non-rotating design	Inspecta 12-466227-02	0
Combi Valves IVC	Inspecta 12-466227-03	0
Cylinder Valves PIN INDEX	Inspecta 12-466227-04	2
Cylinder Valves SMV	Inspecta 12-466227-06	1
Cylinder Valves for Oxygen 300 bar	Inspecta 12-466227-07	0
Combilite Argon	Inspecta 12-466227-08	0
Combihelium Plus	Inspecta 12-466227-09	0
Ministar MIV 300, Ministar 2, E-Ministar, MediVitop	Inspecta 12-466227-11	5
Combilite Helium	Inspecta 12-466227-12	3
Combilite 2QC	Inspecta 12-466227-12	3
Combilite ZX	Inspecta 12-466227-12	3
Combilite Type 4	Inspecta 12-466227-12	3
MediVital, MediVital A, MediVital E	Inspecta 12-466227-12	3
In-line Cylinder Valves with rotating design-GII	Inspecta 15-1006198-100	2
Off-line Cylinder Valves with rotating design-GII	Inspecta 15-1006198-101	3
Chlorine Cylinder Valve	Inspecta 17-1008175-105	0
Charging Valves	Kiwa Inspecta 18-1008175-110	1
Valve for small cylinders	Kiwa Inspecta 18-1008175-114	0
Diaphragm Valve	Kiwa Inspecta 20-1008175-118	0

Malmö, 2020-08-17

Kiwa Inspecta AB
Design Review


Olof Pedersen
Senior Design Review Engineer

Kiwa Inspecta AB

Box 7178 170 07 Solna Sweden Phone: (+46) 10 479 3000 www.kiwa.se
VAT No: SE556190593501

Enclosure 2

Edition: T224-B2 Rev 18

QS Certificate of Assessment No:

VALID INSPECTION PROGRAMME DOCUMENTATION

Doc No	Document Name	Edition	Date
GR 1.03.01	Quality manual-Prirucka jakosti	9	16.6.2020
GR 1.02.01	Quality plan-Plan jakosti	-	23.5.2019
GR 2.02.02	Design and development - Návrh a vývoj	2	17.4.2020
GR 3.04.01	Document control - Řízení dokumentů	4	10.6.2020
GR 2.04.01	Purchasing - Nakupování	2	15.1.2020
SOP 7.5.01	Product traceability - sledovatelnost výrobku	1	06.08.2015
SOP 9	Production process control - Řízení výrobního procesu	35	29.04.2020
SOP 10	Inspection and testing - Kontrola a zkoušení	9	5.2.2020
SOP 11	Metrological regulations	10	7.4.2020
SOP 13	Control of non-conforming products- Řízení neshodného výrobku	11	5.5.2020
SOP 14	Corrective and preventive action - Opatření k nápravě a preventivní opatření	10	11.6.2020
SOP 16	Control of records - Řízení záznamů	2	25.11.2015
SOP 18	Training - Výcvik	11	6.2.2020
GR 2.02.10	TechFile-creation and maintenance, TechFile-tvorba a údržba	3	22.5.2020
SOP 7.1.01	Certification of products acc. to EC directives-certifikace výrobků podle směrnic EU	5	01.02.2017
SOP 15.01	Warehouse management - Řízení skladů	10	3.2.2020

Malmö, 2020-08-17

Kiwa Inspecta AB

Design Review



Olof Pedersen

Senior Design Review Engineer

Kiwa Inspecta AB

Box 7178 170 07 Solna Sweden Phone: (+46) 10 479 3000 www.kiwa.se
Registered office: Solna VAT No: SE556190593501