

EU DECLARATION OF CONFORMITY

Document ID: ZP 03-006_09-02
Manufacturer 's Name: GCE, s.r.o.
Manufacturer 's Address: Žižkova 381, 583 01 Chotěboř, Czech Republic
SRN (Single Registration Number): N/A
Product Group: High Pressure Regulators
Name of the Device: **MEDISELECT II**
Risk Classification: IIb, according to rule 11
GMDN code: 43438

Standards / common specification:

EN ISO 9001:2015	EN ISO 13485:2016
EN ISO 14971:2019	EN ISO 15223-1:2016
EN ISO 15001:2012	ISO 9170-1:2020
EN 1789:2020	EN 1041:2008+A1:2013
EN 62366:2008+A1:2015	EN ISO 10524-1:2018
EN 60601-1:2006+A1:2016	EN 60601-1-2:2015

Notified Body name: DNV Product Assurance AS
Notified Body Address: Veritasveien 3, N-1363 Høvik, Norway
Notified Body Identification number: 2460
EC Certificate Number: 10401-2017-CE-CZS-NA-PS

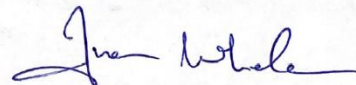
Conformity assessment route:

This declaration of conformity is issued under the sole responsibility of GCE, s.r.o. We hereby declare that the medical device(s) specified above meet the provision of the Regulation MDD 93/42/EEC for medical devices. This declaration is supported by the Quality System approval to ISO 13485:2016 issued by DNV Product Assurance AS

The product is in accordance with Annex II (excluding section 4) of the MDD 93/42/EEC and is safe for declared purpose of use under standard conditions. Any modification to the product, not authorized by us, will invalidate this declaration.

All supporting documentation is retained at the premises of the manufacturer.

Signature:



Place and date of issue:

Chotěboř 01/09/2023

On behalf of manufacturer signed by Ivan Whelan
Person responsible for regulatory compliance

Note: List of variants is in attachment of this document.



Gas Control Equipment

GCE, s.r.o., Žižkova 381, 583 01 Chotěboř, Česká republika, tel.: +420 569 661 111, VAT: CZ27110991,
e-mail: gce@gcegroup.com
www.gcegroup.com

Template number GR 2.02.10 T2 version 1.03

LIST OF VARIANTS

Annex of EU Declaration of conformity with Document ID: ZP 03-006_09-02

Product group: High Pressure Regulators

Name of the device: MEDISELECT II

List of variants:

REF number	Variant name
0720101	MS25 O2 W21.8 SS _ G3/8 S
0720102	MS2 O2 W21.8 _ _ G3/8 S
0720103	MS6 O2 W21.8 G3/8 S
0720104	MS25 O2 W21.8 G3/8 S
0720105	MS6 O2 W21.8 G3/8 S
0720106	MS25 O2 W21.8 G3/8 S
0720107	MS25 O2 W21.8 SS G3/8 G
0720108	MS25 O2 PI G3/8 S
0720111	MS25 O2 W21.8 9/16 S
0720112	MS25 O2 PI G3/8 S
0720114	MS25 O2 W21.8 G3/8 G
0720115	MS25 O2 W21.8 CZ G3/8 G
0720116	MS25 O2 W21.8 DN G3/8 S
0720117	MS2 O2 G3/4 9/16 G
0720118	MS6 O2 G3/4 9/16 G
0720119	MS25 O2 G3/4 9/16 G
0720120	MS25 O2 G3/4 DN 9/16 G
0720121	MS25 O2 G3/4 M12 9/16 G
0720122	MS25 O2 G3/4 9/16 G
0720123	MS25 O2 G3/4 DN 9/16 G
0720124	MS25 O2 G3/4 9/16 G
0720125	MS25 O2 G3/4 DN 9/16 G
0720126	MS25 AIR G5/8D DN 9/16 G
0720127	MS25 CO2 W21.8 9/16 G
0720128	MS25 O2 PI 9/16 G
0720129	MS25 O2 PI DN 9/16 G
0720130	MS25 AIR PI DN 9/16 G
0720131	MS25 O2 PI NF 9/16 G
0720132	MS25 AIR PI NF 9/16 G
0720133	MS25 CO2 PI 9/16 G
0720134	MS2 O2 G5/8NL 9/16 G
0720135	MS6 O2 G5/8NL 9/16 G
0720136	MS25 O2 G5/8NL 9/16 G
0720137	MS25 O2 G5/8NL DN 9/16 G



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REF number	Variant name
0720138	MS25 AIR PI DN 9/16 G
0720140	MS6 O2 SI22 9/16 G
0720141	MS25 O2 SI22 9/16 G
0720142	MS25 O2 SI22 DN 9/16 G
0720143	MS25 O2 SI22 NF 9/16 G
0720144	MS25 AIR G3/4 DN 9/16 G
0720145	MS25 AIR G3/4 NF 9/16 G
0720148	MS6 O2 G3/4 9/16 G
0720149	MS6 O2 G3/4 9/16 G
0720150	MS15 O2 SI22 M12 G
0720151	MS6 O2 SI22 M12 G
0720152	MS15 O2 PI M12 G
0720153	MS15 O2 PI M12 S
0720154	MS25 O2 W21.7 9/16 G
0720156	MS25 O2 W21.7 G1/4 G
0720157	MS25 O2 PI G3/8 G
0720159	MS15 O2 SI22 NF M12 S
0720161	MS15 O2 SI22 9/16 G
0720162	MS6 O2 SI22 9/16 S
0720163	MS15 AIR W24X2 NF M12 G
0720164	MS15 O2 SI22 NF M12 G
0720165	MS2 O2 SI22 M12 G
0720166	MS15 O2/N2O W27X2 NF M12 G
0720167	MS15 AIR M30 NF 9/16 G
0720168	MS15 O2/CO2 M26 9/16 G
0720169	MS2 O2 G3/4 9/16 S
0720170	MS6 O2 G3/4 9/16 S
0720171	MS15 O2 SI22 NF EJ M12 G
0720172	M25 O2 G3/4 2XM12 9/16 G
0720173	MS25 O2 SI22 9/16 G
0720174	MS6 O2 SI22 M12 S
0720175	MS15 O2 SI22 M12 S
0720176	MS15 O2 SI22 9/16 S
0720180	MS15 O2 SI22 9/16 S
0720182	MS15 O2 SI22 NF EJ 9/16 S
0720183	MS6 O2 SI22 9/16 S
0720185	MS25 O2 G3/4 9/16 S
0720186	MS25 O2 G5/8BS G3/8 G
0720190	MS15 O2 PI 9/16 G
0720191	MS15 O2 SI22 NF 9/16 G
0720192	MS2 O2 SI22 9/16 G
0720193	MS15 O2 SI22 NF EJ 9/16 G



LIST OF VARIANTS

REF number	Variant name
0720195	MS6 O2 W21.7 G1/4 G
0720196	MS6 O2 W21.7 9/16 G
0720197	MS25 O2 W21.8 9/16 G
0720198	MS6 O2 W21.8 G3/8 G
0720199	MS25 O2 G3/4 SS G3/8 G
0720201	MS25 O2 W21.8 G3/8 G
0720204	MS6 O2 G3/4 9/16 G
0720205	MS25 O2 G3/4 9/16 G
0720206	MS25 O2 G3/4 DN 9/16 S
0720207	MS25 O2 G5/8NL DN 9/16 S
0720208	MS25 O2 PI 9/16 S
0720209	MS25 O2 G3/4 SS 9/16 S
0720210	MS25 O2 G3/4 RT 9/16 G
0720213	MS6 O2 M19 9/16 G
0720214	MS25 O2 G5/8NL 9/16 G
0720215	MS2-4 O2 G5/8BS G3/8 S
0720216	MS25 O2 G5/8BS G3/8 S
0720217	MS25 O2 W21.8 DN 9/16 G
0720218	MS2 O2 W21.8 9/16 G
0720219	MS2-4 O2 G5/8BS G3/8 G
0720220	MS25 O2 W21.8 SS 9/16 G
0720221	MS2 O2 W21.8 G3/8 G
0720222	MS6 O2 W21.8 9/16 G
0720223	MS25 O2 PI 9/16 G
0720224	MS6 O2 PI 9/16 G
0720225	MS2 O2 PI 9/16 G
0720226	MS6 O2 W21.8 9/16 G
0720227	MS25 O2 W21.8 SS G3/8 S
0720229	MS2 AIR G5/8 G3/8 S
0720230	MS25 O2 W21.7 NF G1/4 G
0720231	MS15 O2 PI M12 S
0720233	MS15 M W30X2 M12 S
0720234	MS2 O2 SI22 M12 S
0720235	MS15 N2 SI21 M12 S
0720236	MS15 AIR W24X2 M12 S
0720237	MS15 O2 PI NF M12 S
0720238	MS2 O2 PI M12 S
0720239	MS15 AIR W24X2 NF M12 S
0720240	MS25 O2 G3/4 G3/8 9/16 G
0720242	MS15 O2 SI22 M12 S
0720243	MS15 O2 SI22 NF EJ M12 S
0720244	MS15 AIR PI NF M12 S



LIST OF VARIANTS

REF number	Variant name
0720245	MS15 N2O CGA326 9/16 G
0720246	MS25 O2 PI 9/16 G
0720247	MS25 O2 G5/8BS 9/16 G
0720248	MS25 O2 PI BS 9/16 G
0720249	MS25 O2 G5/8BS BS 9/16 G
0720252	MS2-4 O2 G5/8BS _ _ 9/16 G
0720253	MS25 O2 G3/4 9/16 G
0720254	MS15 O2 SI22 9/16 S
0720255	MS15 N2 SI21 M12 G
0720256	MS25 O2 G5/8NL DN 9/16 G
0720258	MS25 O2 W21.8 SS 9/16 G
0720259	MS6 O2 W21.8 9/16 G
0720260	MS2 O2 W21.8 9/16 G
0720261	MS6 O2 PI 9/16 G
0720262	MS25 O2 PI SS 9/16 G
0720263	MS25 O2 W21.8 9/16 G
0720264	MS25 O2 W21.8 CZ G3/8 G
0720265	MS15 AIR PI BS 9/16 G
0720266	MS2 O2 W21.7 9/16 G
0720267	MS2 O2 W21.7 G1/4 G
0720268	MS25 O2 G5/8CH 9/16 G
0720269	MS25 O2 W21.8 CM 9/16 S
0720270	MS25 AIR W30 NF G1/4 G
0720271	MS25 O2 G5/8CH NF 9/16 G
0720272	M25 O2 G5/8NL 2XM12 9/16 G
0720273	MS2 O2 CGA540 9/16 G
0720274	MS6 O2 CGA540 9/16 G
0720275	MS25 O2 CGA540 9/16 G
0720276	MS2 O2 W21.8 9/16 S
0720278	MS6 O2 PI 9/16 G
0720284	MS15 O2 W21,8 9/16 S
0720289	MS6 O2 W21.8 9/16 S
0720290	MS3 O2 CGA540 9/16 S
0720291	MS3 O2 PI 9/16 S
0720292	MS25 O2 SI22 BS 9/16 G
0720293	MS25 O2 G5/8CH DS 9/16 G
0720295	MS25 CO2 W27x2 SS 9/16 G
0720296	MS25 O2 G5/8BS 9/16 G
0720297	MS25 O2 PI 9/16 G
0720299	MS25 O2 G3/4 9/16 G
0720301	M25 O2 G3/4 M12 DIN 9/16 G
0720302	MS25 O2 PI 2xDISS 9/16 G



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REF number	Variant name
0720303	MS12 Xe W21,8 9/16 G
0720304	MS25 O2 SI22.91 9/16 G
0720307	MS25 O2 G5/8CH DIN 9/16 G
0720308	MS25 O2 W21.8x14 9/16 G
0720309	MS25 O2 BS PI 9/16 G
0720310	MS25 O2 BS G5/8 - 9/16 G
0720311	MS25 O2 W30x2 SS 9/16 G
0720312	MS25 AIR G5/8 BS 9/16 G
0720313	MS25 CO2 G3/4" 9/16 G
0720314	MS25 O2 W30X2 9/16 G
0720315	MS2 O2 G3/4 9/16 G
0720316	MS25 O2 G3/4 NIST 9/16 G
0720317	MS25 O2 G3/4 DIN 9/16 S
0720318	MS2 O2 G5/8BS 9/16 G
0720319	MS25 O2 PI 9/16 G
0720320	MS25 AIR G5/8BS BS 9/16 G
0720321	MS25 AIR PI 9/16 G
0720322	MS4 O2 PI 9/16 S
0720323	MS3 O2 CGA540 9/16 S
0720324	MS3 O2 CGA540 9/16 S
0720325	MS25 O2 W21.8 SS 9/16 G
0720326	MS3 O2 PI 9/16 G
0720327	MS3 O2 CGA540 9/16 G
0720328	MS25 O2 PI 2SIS _ G1/4 S
0720329	MS15 O2 PI 2SIS _ G1/4 S
0720330	MS15 O2 PI __ G1/4 S
0720331	MS15 O2 PI __ G1/4 S
0720332	M25 O2 PI 2xDN 9/16 G
0720333	M25 O2 W21.8 2xSS 9/16 G
0720334	MS25 O2 W21.7 UN _ G1/4 G
0720335	MS15 O2 CGA540 NF _ 9/16 G
0720336	MS25 O2 CGA540 DS _ 9/16 G
0720337	MS25 O2 PI DS _ 9/16 G
0720338	MS2 O2 PI __ G1/4 S
0720339	MS3 O2 PI __ G1/4 S
0720340	MS15 O2 CGA540 __ 9/16 S
0720341	MS15 O2 PI __ 9/16 S
0720342	MS25 AIR PI BS _ 9/16 G
0720343	MS25 O2 PI BS _ 9/16 G
0720344	MS25 O2 W21.8 CZ _ 9/16 G
0720345	MS25 O2 CGA540 BS _ 9/16 G
0720346	MS25 AIR CGA580 BS _ 9/16 G



LIST OF VARIANTS

REF number	Variant name
0720347	MS15 O2 W21.8 SIS _ 9/16 G
0720348	MS25 AIR CGA346 BS _ 9/16 G
0720349	MS25 AIR CGA346 __ 9/16 G
0720350	MS25 O2 CGA540 DN _ 9/16 G
0720351	MS25 O2 W21.7 DN _ G1/4 G
0720352	MS15 O2 PI __ 9/16 G
0720353	MS15 O2 G5/8BS __ 9/16 G
0720354	MS15 O2 CGA540 __ 9/16 G
0720355	MS25 O2/N2O W21.8 SS _ 9/16 G
0720356	MS2 O2 W21.8 __ 9/16 G
0720357	MS6 O2 W21.8 __ 9/16 G
0720358	MS15 O2 W21.8 __ 9/16 G
0720359	MS15 O2 CGA540 __ 9/16 G
0720360	MS25 O2 W30X2 G3/8 _ 9/16 G



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