

# EU DECLARATION OF CONFORMITY

**Document ID:** ZP 03-006\_09-01  
**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:** **MEDIREG 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

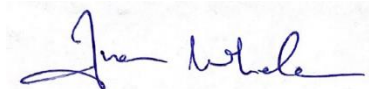
## Conformity assessment route:

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

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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\_09-01

Product group: High Pressure Regulators

Name of the device: MEDIREG II

List of variants:

REF number	Variant name
0724101	MR O2/N2O PI SS S
0724102	MR O2 W21.8 SS S
0724103	MR15F O2 W21.8 _ _ G3/8 S
0724104	MR N2O G3/8 SS S
0724105	MR AIR G5/8 SS S
0724106	MR CO2 W27X2 SS S
0724107	MR O2 CGA540 SS S
0724108	MR O2 PI SS S
0724109	MR15F O2 W21.8 9/16 S
0724110	MR15F O2 CGA540 9/16 S
0724111	MR O2 W21.8 CZ G
0724112	MR N2O G3/8 CZ G
0724113	MR AIR G5/8 CZ G
0724114	MR15F O2 G3/4 9/16 G
0724115	MR15F AIR G5/8D 9/16 G
0724116	MR4 O2 G3/4 G3/8 G
0724117	MR O2 G3/4 M12 G
0724118	MR O2 G3/4 DN G
0724119	MR O2 G3/4 NF G
0724120	MR AIR G5/8 M20 G
0724121	MR AIR G5/8 DN G
0724122	MR AIR G5/8 NF G
0724123	MR N2O G3/4 M14X1 G
0724124	MR N2O G3/4 DN G
0724125	MR N2O G3/8 M14X1 G
0724126	MR N2O G3/8 DN G
0724127	MR20 O2 G3/4 9/16 G
0724128	MR O2 PI DN G
0724129	MR O2 PI NF G
0724130	MR AIR PI DN G
0724131	MR N2O PI DN G
0724132	MR CO2 PI DN G
0724133	MR O2 G5/8NL DN G
0724134	MR O2 SI22 DN G
0724135	MR O2 SI22 NF G



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REF number	Variant name
0724136	MR AIR G3/4 DN G
0724137	MR AIR G3/4 NF G
0724138	MR15F O2 W21.8 9/16 G
0724140	MR6 O2 G3/4 RT G
0724141	MR O2 G3/4 G3/8 G
0724142	MR O2 G3/4 DN G
0724143	MR O2 PI G3/8 G
0724144	MR O2 PI NF G
0724145	MR AIR W24X2 NF G
0724146	MR O2/N2O M19 NF G
0724147	MR N2O SI26 NF G
0724148	MR O2 W21.8 DN S
0724149	MR AIR G5/8 SS G
0724150	MR CO2 W21.8 G3/8 G
0724151	MR O2/N2O PI BS G
0724152	MR O2 W21.8 SS G
0724153	MR O2 W21.7 NF G
0724154	MR AIR W30 NF G
0724156	MR AIR G5/8 SS G
0724157	MR O2/N2O W21.8 SS G
0724158	MR N2O G3/8 SS G
0724159	MR CO2 W27X2 SS G
0724160	MR O2 W21.8 DN G
0724161	MR N2O G3/8 DN G
0724162	MR O2 G3/4 SS G
0724163	MR AIR G5/8 DN S
0724164	MR4 O2 G3/4 G3/8 S
0724165	MR20 O2 G3/4 RT S
0724166	MR O2 G3/4 DN S
0724167	MR O2 G3/4 G3/8 S
0724168	MR N2O G3/8 SS G
0724169	MR O2/N2O PI SS G
0724171	MR AIR G5/8 G3/8 S
0724172	MR O2 G3/4 CZ G
0724173	MR N2O W21.8 CZ G
0724174	MR O2 SI22 NF S
0724175	MR AIR W24X2 NF S
0724176	MR N2O SI26 NF S
0724177	MR AIR G3/4 SS G
0724178	MR N2O W21.8 SS G
0724179	MR O2 G5/8NL G3/8 G
0724180	MR AIR W21.8 DN G
0724182	MR O2 G3/4 G3/8 G
0724183	MR O2 W21.8 9/16 G



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REF number	Variant name
0724184	MR4 O2 G3/4 9/16 G
0724185	MR O2 W21.7 G1/4 G
0724186	MR O2 W21.7 G1/4 ELG G
0724187	MR15F O2 W21.7 G1/4 G
0724188	MR15F W21.7 9/16 G
0724189	MR AIR M30 NF G
0724190	MR N2O W21.8 DN G
0724191	MR6 O2 PI G3/8 S
0724192	MR20 CO2 W21.8 9/16 G
0724193	MR AIR G5/8CH G1/4 G
0724194	MR O2 G5/8 G1/4 G
0724195	MR O2/N2O G5/8 BS G
0724196	MR AIR PI SS G
0724197	MR N2O G3/8 NF G
0724198	MR O2 G5/8 DN G
0724199	MR AIR G5/8 UQ S
0724200	MR O2 G5/8 G1/4 ELG G
0724201	MR O2 W21,8 SS ELG G
0724202	MR N2O G3/8 G1/4 G
0724204	MR O2 G3/4 DN ELG G
0724205	MR O2 G5/8NL DN ELG G
0724206	MR O2 PI DN ELG G
0724208	MR AIR PI DN ELG G
0724209	MR O2 G3/4 G3/8 G
0724210	MR O2 PI SS G
0724211	MR CO2 W21,8 DN G
0724212	MR CO2 W27x2 UN G
0724213	MR CO2 SI21,7 NF G
0724214	MR AIR G5/8 SS G
0724215	MR CO2 PI DS G
0724216	MR O2 CGA540 NF G
0724217	MR N2O SI26 G1/4 G
0724218	MR O2 W21.7 UN G
0724219	MR AIR W30 UNI G
0724221	MR15F O2 PI 9/16 G
0724222	MR O2 SI22 BS G
0724223	MR15F O2 SI22 9/16 G
0724224	MR O2 CGA540 G1/4 G
0724225	MR N2O CGA326 G1/4 G
0724226	MR N2O W11/16 G1/4 G
0724227	MR5F O2 G3/4 9/16 G
0724228	MR O2 SI22 G1/4 G
0724229	MR AIR W30 G1/4 G
0724230	MR XE W21,8 G3/8 G



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REF number	Variant name
0724231	MR O2 PI DISS G
0724236	MR II O2 PI G3/8 ELG G
0724237	MR O2 CGA540 DIN G
0724238	MR O2 G3/4 NS G
0724239	MR AIR G5/8 NIST G
0724240	MR O2 G5/8 NS G
0724241	MR O2 PI NIST G
0724242	MR AIR PI NIST G
0724243	MR O2 PI BS G
0724244	MR O2 G5/8 BSI G
0724245	MR O2 G5/8CH DIN G
0724246	MR O2 W30x2 DIN G
0724247	MR AIR G3/4 DIN G
0724248	MR O2 CGA540 G1/4 ELG G
0724249	MR CO2 CGA540 DISS G
0724250	MR II O2 W21.7 WH0,4 M14X1,25
0724251	MR II N2O G3/8 BH0,4 M14x1,25
0724252	MR4 AIR G5/8 9/16 G
0724253	MR15F O2 G5/8BS 9/16 G
0724254	MR15F O2 CGA540 9/16 G
0724255	MR II AR W24x2 RECTUS G
0724256	MR II AR W24x2 RECTUS PT G
0724257	MR12 AIR G5/8 9/16 G
0724258	MR II O2,W21,7, G1/4 G
0724259	MR II CO2 PI NIST G
0724260	MR II O2 G3/4 WH0,4 M14X1,25 S
0724261	MR II AR W24x2 HN S
0724262	MR II O2 SI22 WH 0,4 M14X1,25
0724263	MR II N2O SI26 BH 0,4 M14x1,25
0724264	MR II AIR G3/4 DN PT G
0724265	MR II O2 SI22 DN PT G
0724266	MR II AR W22x14 RECTUS PT G
0724267	MR II AR W24.32x14 RECTUS PT G
0724268	MR II AR G5/8 RECTUS PT G
0724269	MR II AR W21.8x14 RECTUS PT G
0724270	MR II AR CGA580 RECTUS PT G
0724271	MR II AR CGA580 USA RECTUS PT
0724272	MR O2 G3/4 BS G
0724273	MR O2 G5/8 WH 0,4 M14x1,25 RH
0724274	MR N2O W11/16 BH 0.4 W14x1,25
0724275	MR O2 W24X2 BS __ G
0724276	MR O2 W24X2 G3/8 __ G
0724278	MR O2 CGA540 BS G
0724279	MR O2 W21.8 G3/8 G



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REF number	Variant name
0724280	MR II N2O PI G1/4 G
0724281	MR II O2 PI G1/4 G
0724282	MR O2 W21,8 SS PT G
0724283	MR AIR G5/8BS BS G
0724284	MR N2O G3/8 BS G
0724285	MR O2 G3/4 SS ELG G
0724286	MR O2 PI SIS __ S
0724287	MR N2O PI SIS __ S
0724288	MR O2/N2O PI SIS __ S
0724289	MR AIR PI SIS __
0724290	MR O2 CGA540 DS G
0724291	MR N2O CGA326 DS G
0724292	MR AIR CGA590 DS G
0724293	MR O2 W21,7 DN G
0724294	MR O2/N2O PI NF __ G
0724295	MR15F O2 G5/8BS __ 9/16 G
0724296	MR N2O W21.8 M14LH BH4 _ G
0724297	MR N2O CGA326 NF __ G
0724298	MR AIR G5/8 DN __ G
0724299	MR N2O PI BS __ G
0724300	MR AIR CGA580 DS __ G
0724303	MR N2O PI M14LH BH4 _ G
0724304	MR O2 PI M14RH WH4 _ G
0724305	MR O2 G3/4 G1/4 PTBH _ G
0724306	MR CO2 W21,8 G1/4 PTBH _ G
0724307	MR AIR PI BS __ G
0724308	MR O2 W21.8 NF __ G
0724309	MR AIR CGA346 BS __ G
0724310	MR O2 W21,7 G1/4 __ G
0724311	MR AR W24X2 RT PTBH _ G
0724312	MR CO2 W21.8 SS __ G
0724313	MR O2 G3/4 __ G3/8 G
0724314	MR N2O CGA326 BS __ G
0724315	MR O2 G3/4 _ PTBH G3/8 G
0724316	MR O2 W21.7 __ G3/8 G
0724317	MR O2 W21.7 __ G3/8 G
0724318	MR O2 W21.7 _ PTBH G3/8 G
0724319	MR O2 W21.7 __ G3/8 G
0724320	MR O2 W21.8 __ G3/8 G
0724321	MR O2 W21.8 __ G3/8 G
0724322	MR O2 W21.8 _ PTBH G3/8 G
0724323	MR O2 G5/8NL __ G3/8 G
0724324	MR O2 G5/8NL __ G3/8 G
0724325	MR O2 G5/8NL _ PTBH G3/8 G



# LIST OF VARIANTS

REF number	Variant name
0724330	MR O2 PI __ G3/8 G
0724331	MR O2 PI __ G3/8 G
0724332	MR O2 PI _ PTBH G3/8 G
0724333	MR O2 SI22 __ G3/8 G
0724334	MR O2 SI22 __ G3/8 G
0724335	MR O2 SI22 _ PTBH G3/8 G
0724336	MR O2 SI22 __ G3/8 G
0724337	MR O2 G5/8BS __ G3/8 G
0724338	MR O2 G5/8BS __ G3/8 G
0724339	MR O2 G5/8BS _ PTBH G3/8 G
0724340	MR O2 G5/8BS __ G3/8 G
0724341	MR O2 G3/4 __ G3/8 G
0724342	MR O2 PI G3/8 G
0724343	MR O2 PI BS __ G
0724344	MR O2 G5/8BS BS __ G
0724345	MR O2 PI BS __ G
0724346	MR O2 G5/8BS BS __ G
0724347	MR AIR PI BS __ G
0724348	MR AIR G5/8BS BS G
0724350	MR O2 PI BS __ S
0724351	MR N2O PI BS __ S
0724352	MR O2/N2O PI BS __ S
0724353	MR AIR PI BS __ S



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