

EU DECLARATION OF CONFORMITY

Document ID: ZP 02-005_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: Pressure regulators integrated with cylinder valve
Name of the Device: **MEDIVITAL**
Risk Classification: IIb, according to rule 11
GMDN code: 60970

Standards / common specification:

EN ISO 10524-3:2019	EN ISO 11117:2019
EN 1789:2007+A1:2010+A2:2014	EN ISO 15001:2011
EN ISO 10297:2014	ISO 9001:2015
EN ISO 15996:2017	ISO 13485:2016
EN 62366:2008+A1:2015	EN 60601-1-11:2015
EN 1041:2008+A1:2013	EN ISO 14971:2012
EN ISO 15223-1:2016	

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 25/08/2022

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 02-005_09-01

Product group: Pressure regulators integrated with cylinder valve

Name of the device: MEDIVITAL

List of variants:

REF number	Variant name
0718000	MV25 O2 17E G5/8NL DN G
0718001	MV15 O2 25E W21.7 G
0718002	MV15 O2 25E W21.7 NF G
0718003	MV15 O2 17E W21.7 G
0718004	MV15 O2 17E W21.7 UN G
0718005	MV15 O2 25E W21.7 UN G
0718006	MV15 O2 17E W21.7 NF G
0718007	MV25 O2 17E W24x2 BS G
0718008	MV25 O2 25E W24x2 DN G
0718009	MV25 O2 25E W24x2 G
0718010	MV25 O2 25E G5/8NL DN G
0718011	MV6 O2 25E G5/8NL DN G
0718012	MV6 O2 17E G5/8NL DN G
0718013	MV25 O2 25E G5/8NL DN S
0718014	MV25 O2 17E 5/8NL DN S
0718015	MV15 O2 25E SI22 NF G
0718016	MV15 O2 25E G3/4 DN 9/16 G
0718017	MV25 O2 17E W24x2 G
0718018	MV15 O2 25E W24x2 CZ G
0718019	MV6 O2 17E G5/8NL G
0718020	MV25 O2 25E G5/8NL G
0718021	MV25 O2 17E W21.8 SS G
0718022	MV25 O2 25E W21.8 SS G
0718023	MV15 O2 17E W24x2 NF G
0718024	MV15 O2 M18 W30x2 G
0718025	MV15 O2/N2O 25E W27x2 NF G
0718026	MV25 AIR 25E W30x2 DN G
0718027	MV25 AIR 17E W30x2 DN G
0718028	MV15 O2 25E SI22 BS G
0718030	MV O2 25E G5/8NL NF G
0718031	MV25 O2 25E SI22 S
0718032	MV25 O2 25E W21.7 NF G
0718033	MV25 O2 17E G5/8NL NF G
0718037	MV15 O2 17E W30x2 BS S
0718038	MV15 O2 17E W21.7 BS S



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Template number GR 2.02.10 T2 version 1.03

LIST OF VARIANTS

REF number	Variant name
0718042	MV25 O2 25E W30x2 DN G
0718043	MV25 O2 17E W30x2 DN G
0718044	MV15 O2 25E W30x2 NF G
0718045	MV15 O2 25E W24X2S NF S
0718046	MV15 AIR 17E W24x2 NF G
0718047	MV15 AIR 25E W24x2 NF G
0718048	MV25 O2 17E W24x2 DN G
0718049	MV15 O2 17E W24x2 G
0718050	MV25 O2 25E G3/4 SS G
0718051	MV25 O2 17E G3/4 SS G
0718052	MV15 O2 18T W24x2 G
0718053	MV15 O2 25E G3/4 SS G
0718054	MV25 O2 25E W24x2 NF G
0718055	MV15 AIR 25E W24x2 NF G
0718056	MV15 O2 17E G5/8NL DN G
0718058	MV25 O2/N2O 18T W27x2 G
0718059	MV15 O2 25E W24x2 BS G
0718060	MV25 O2 25E G3/4 DN G
0718061	MV25 O2 17E W24x2 S
0718062	MV15 O2 25E SI22 S
0718063	MV15 O2 25E W30x2 DN G
0718064	MV15 O2 25E W30x2 NF G
0718065	MV15 O2 18T W24x2 BS G
0718066	MV15 O2 25E W21.7 S
0718067	MV15 O2 25E W21.7 NF S
0718068	MV15 O2 17E W21.7 S
0718069	MV15 O2 17E W21.7 UN S
0718070	MV15 O2 25E W21.7 UN S
0718071	MV15 O2 17E W21.7 NF S
0718072	MV15 O2 25E W21.7 BS S
0718073	MV15 O2 17E G3/4S S
0718074	MV25 O2 25E W21.8S SS BH S
0718075	MV25 O2 M18 W21.8S SS BH S
0718076	MV15 O2 17E W24x2 CZ G
0718078	MV15 AIR 25E W24x2 DN G
0718079	MV15 O2 25E G3/4S S
0718080	MV15 O2 25E G3/4 DN BH G
0718081	MV15 O2 25E SI22 NF BH S
0718082	MV15 O2 25E SI22 DN BH S
0718083	MV O2/N2O 18T W27x2 BS G
0718084	MV15 AIR 17E W24x2 DN BH G
0718085	MV15 O2 17E W30x2 G
0718087	MV15 O2/N2O 17E W27x2 NF G
0718088	MV25 AIR 25E G5/8D SS BH S



LIST OF VARIANTS

REF number	Variant name
0718089	MV15 O2 17E W30x2 DN BH G
0718090	MV15 O2 M18 W30x2 DN BH G
0718091	MV15 O2 25E W30x2 BS G
0718092	MV25 AIR 25E G5/8D DN G
0718093	MV O2/N2O 17E W27x2 NF G
0718094	MV25 O2 25E W30x2 DN S
0718095	MV25 O2 17E W30x2 DN S
0718097	MV25 O2 25E W24x2 BS G
0718098	MV15 O2 17E W21.7 BS S
0718099	MV15 O2 17E G3/4 DN BH G
0718100	MV6 O2 17E G5/8NLS S
0718101	MV6 O2 25E G5/8NLS S
0718102	MV15 O2 25E G5/8NLS DN S
0718103	MV25 O2 M18 W30x2 DN G
0718104	MV25 O2 25E W24x2 G
0718105	MV25 O2 25E W24x2 DN BH G
0718106	MV25 O2 25E W24x2 NF BH G
0718107	MV O2/N2O 25E W27x2 BS G
0718108	MV15 O2 25E W24x2 SIS BH S
0718109	MV15 O2 17E W30x2 NF G
0718110	MV25 O2 25E G3/4 DN G
0718111	MV25 O2 17E G3/4 DN BH G
0718112	MV15 O2 25E W24x2 BS S
0718113	MV15 O2 25E W24x2S BS S
0718114	MV15 AIR 25E W24x2 BS G
0718115	MV25 O2 M18 W30x2 DN BH G
0718116	MV15 O2 25E W30x2 NF BH S
0718117	MV15 O2 25E W30x2 DN BH S
0718118	MV6 O2 17E W24x2 DN BH G
0718119	MV15 O2 17E G5/8NLS S
0718120	MV25 O2 M18 W30x2 BS G
0718121	MV15 O2 25E SI22 G
0718122	MV15 O2 3/4UNF CGA577 DS S
0718123	MV25 O2 3/4UNF CGA577 DS S
0718124	MV25 O2 25E G3/4 DN G
0718125	MV15 O2 M18 W24x2 BS G
0718126	MV25 O2 3/4UNF W24x2 DS G
0718127	MV25 O2 M18x1,5 W24x2 DS G
0718128	MV15 HeO2 25E W30x2 SIS G
0718129	MV15 O2 17E W24x2 DN G
0718130	MV O2/N2O 25E W27x2 SS G
0718131	MV25 O2 17E G3/4 DN G
0718132	MV15 O2 25E W30x2 SIS BH S
0718133	MV15 O2 17E W21.7 BS S



LIST OF VARIANTS

REF number	Variant name
0718136	MV15 O2 25E W21.7 NF G
0718137	MV15 O2 25E W24x2 SIS G
0718138	MV15 O2 25E W24x2 SIS S
0718139	MV15 O2 25E W24x2 BS S
0718140	MV15 O2 25E W24x2S BS S
0718141	MV15 O2 17E W24x2S BS S
0718142	MV O2/N2O 18T W27x2 BS G
0718143	MV25 AIR 25E W24x2 BS G
0718144	MV15 O2 25E W21.7 G
0718145	MV15 O2 17E W21.7 G
0718146	MV15 O2 17E W21.7 NF G
0718147	MV25 O2 25E W24x2 DN S
0718149	MV15 O2/N2O 25E W27x2 SS G
0718150	MV O2/N2O 25E W27x2 BS G
0718152	MV15 O2 25E SI22 DN BH G
0718153	MV15 He/O2 25E W30x2 BS S
0718154	MV15 AIR 25E W24x2 BS S
0718155	MV O2/N2O 25E W27x2 BS S
0718156	MV O2/N2O 25E W27x2 BS S
0718157	MV15 O2 25E W30x2 G
0718158	MV O2/N2O 17E W27x2 BS S
0718159	MV25 O2 25E SI22 G
0718160	MV15 O2 25E W21.7 UN G
0718161	MV15 O2 17E W21.7 UN G
0718162	MV15 O2 25E W24x2 DN G
0718163	MV25 O2 17E G5/8NL DN BH G
0718164	MV25 O2 3/4UNF CGA577 DS S
0718165	MV25 O2 3/4NGT CGA540 DS S
0718166	MV25 O2 25E G5/8NL DN BH G
0718167	MV15 O2 M18 G3/4S S
0718168	MV25 O2 3/4UNF CGA540 DS S
0718171	MV25 O2 3/4UNF CGA577 DS G
0718172	MV25 O2 25E W24x2 DN S
0718174	MV25 AIR 17E W30x2 DN BH G
0718175	MV25 AIR 25E W30x2 DN BH G
0718176	MV25 O2 3/4NGT CGA540 DS S
0718177	MV15 O2 25E W21.7 G
0718179	MV25 O2 3/4NGT CGA540 DS S
0718180	MV15 O2 25E W24X2S DN S
0718181	MV O2/N2O 25E W27x2 NF G
0718182	MV15 O2 17E W30x2 BS S
0718183	MV25 O2 3/4UNF CGA540 DS S
0718184	MV15 O2 3/4UNF CGA577 DS S

