

EU DECLARATION OF CONFORMITY

Document ID: ZP 04-007_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: Suction Equipment
Name of the Device: **MEDIEJECT II**
Risk Classification: IIa, according to rule 11
GMDN code: 63647

Standards / common specification:

EN ISO 9001:2015	EN ISO 13485:2016
EN ISO 14971:2019	EN ISO 15223-1:2016
EN ISO 15001:2011	EN ISO 10079-3:2022
EN ISO 10079-4:2021	EN 1041:2008+A1:2013
EN 1789:2020	EN 837-1:2013
EN 62366:2008+A1:2015	EN ISO 9170-1:2020

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

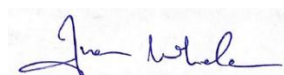
Conformity assessment route:

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 27/03/2025

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 04-007_09-01

Product group: Suction Equipment

Name of the device: MEDIEJECT II

List of variants:

REF number	Variant name
0735400	MEJII _ O2-AIR SS _ _ G
0735401	MEJII _ O2 SS90 PM1 _ G
0735403	MEJII _ O2-AIR SS _ _ S
0735404	MEJII _ O2 SS90 PM1 _ S
0735405	MEJII _ O2 SS PM1 _ S
0735406	MEJII _ AIR SS90 PM1 _ S
0735407	MEJII _ AIR SS PM1 _ S
0735408	MEJII _ O2 SS90 CP1 _ S
0735409	MEJII _ O2 SS CP1 _ S
0735410	MEJII _ AIR SS90 CP1 _ S
0735411	MEJII _ AIR SS CP1 _ S
0735412	MEJII _ O2 SS90 NOPLATE 1m _ S
0735413	MEJII _ O2 BS _ _ G
0735414	MEJII _ O2-AIR DN _ _ G
0735415	MEJII _ O2-AIR DN120 PM1.5 _ G
0735416	MEJII _ O2-AIR DN120 CP1.5 _ G
0735417	MEJII _ O2 NF _ _ G
0735418	MEJII _ O2 NF90 PM1.5 _ G
0735419	MEJII _ O2 NF90 CP1.5 _ G
0735420	MEJII _ AIR NF _ _ G
0735421	MEJII _ AIR NF90 PM1.5 _ G
0735422	MEJII _ AIR NF90 CP1.5 _ G
0735423	MEJII _ O2 UN _ _ G
0735424	MEJII _ O2 UN90 PM1.5 _ G
0735425	MEJII _ O2 UN90 CP1.5 _ G
0735426	MEJII _ AIR UN _ _ G
0735427	MEJII _ AIR UN90 PM1.5 _ G
0735428	MEJII _ AIR UN90 CP1.5 _ G
0735429	MEJII _ O2 BS90 PM1.5 _ G
0735430	MEJII _ O2 BS90 CP1.5 _ G
0735431	MEJII _ AIR BS _ _ G
0735432	MEJII _ AIR BS90 PM1.5 _ G
0735433	MEJII _ AIR BS90 CP1.5 _ G



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REF number	Variant name
0735434	MEJII _ O2 NS PM _ G
0735435	MEJII _ O2-AIR CZ PM1.5 _ G
0735436	MEJII _ AIR SS90 CP2.2 _ S
0735437	MEJII _ O2 NS CP _ G
0735438	MEJII _ AIR NS PM _ G
0735439	MEJII _ AIR NS CP _ G
0735440	MEJII _ AIR SS PM1.7 _ S
0735441	MEJII _ O2 SS90 PM3 _ S
0735442	MEJII _ O2 SS PM3 _ S
0735443	MEJII _ AIR SS90 PM3 _ S
0735444	MEJII _ AIR SS PM3 _ S
0735445	MEJII _ AIR SS90 CP3 _ S
0735446	MEJII _ O2 DS _ _ G
0735447	MEJII _ AIR CB _ _ G
0735448	MEJII _ AIR MD _ _ G
0735449	MEJII _ AIR PD _ _ G
0735450	MEJII _ AIR NS CE50 _ G
0735451	MEJII _ AIR CH _ _ G
0735452	MEJII _ AIR DS _ _ G
0735453	MEJII _ AIR OH _ _ G
0735454	MEJII _ O2 CZ _ _ G
0735455	MEJII _ AIR SS90 CP1.6 _ S
0735456	MEJII _ AIR SS CP1.6 _ S
0735457	MEJII _ AIR SS90 PM1.6 _ S
0735458	MEJII _ AIR SS PM1.6 _ S
0735459	MEJII _ O2 SS90 CP1.6 _ S
0735460	MEJII _ O2 SS CP1.6 _ S
0735461	MEJII _ O2 SS90 PM1.6 _ S
0735462	MEJII _ O2 SS PM1.6 _ S
0735463	MEJII _ O2 SS90 PM0.6 _ S
0735464	MEJII _ AIR CZ _ _ G
0735465	MEJII _ O2 CZ PM3 _ G
0735466	MEJII _ AIR CZ PM3 _ G
0735467	MEJII _ AIR G3/8 _ _ G
0735468	MEJII _ O2 G38M _ _ G
0735500001	MEJII _ AIR SS90 PM1.5 _ S
0735500002	MEJII _ AIR SS90 CP1.5 _ G
0735500003	MEJII _ O2 SS PM2 _ S
0735500004	MEJII _ AIR SS CP1.5 _ S
0735500005	MEJII _ O2 SS PM1 _ G
0735500006	MEJII _ O2-AIR NS PM _ G
0735500007	MEJII _ AIR NS CP _ S



LIST OF VARIANTS

REF number	Variant name
0735500008	MEJII _ O2 SS90 CP0.5 _ S
0735500012	MEJII _ AIR DN _ _ G
0735500031	MEJII _ AIR SS90 PM0.5 _ S



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