

EU DECLARATION OF CONFORMITY

Document ID: ZP 03-006_09-06
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: **SABRE ELITE**
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 15001:2011	ISO 9170-1:2020
EN 1789:2020	EN 1041:2008+A1:2013
EN 62366:2008+A1:2015	EN ISO 10524-1:2018
ISO 80601-2-67	

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

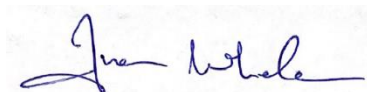
Conformity assessment route:

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 19/02/2024

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_09-06

Product group: High Pressure Regulators

Name of the device: SABRE ELITE

List of variants:

REF number	Variant name
2001647	SABRE ELITE BS PROBE, BOXED
2010294	SABRE ELITE BS PROBE, BOXED
2001635	ELH-L-BULL-12F1 SABRE ELITEBOX
2001636	ELH-L-BENE-12F1 SABRE ELITEBOX
2001637	ELH-L-PI.O-12F1 SABRE ELITEBOX
2001638	ELH-L-DIN9-12F1 SABRE ELITEBOX
2001639	ELH-L-DN6O-12F1 SABRE ELITEBOX
2001640	ELH-L-US.O-12F1 SABRE ELITEBOX



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