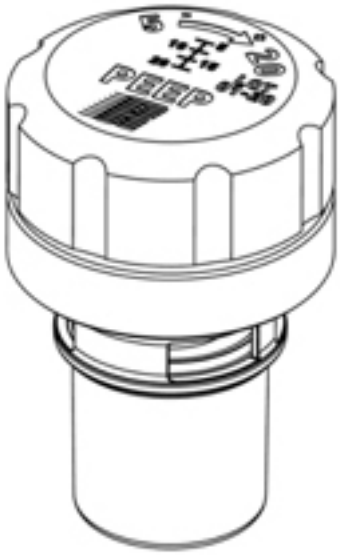
# REDFLUID PEEP VALVE

STANDARD DESIGN AND ALVEOLAR RECRUITMENT | MODELO ESTÁNDAR Y DE RECRUTAMIENTO ALVEOLAR

Portable Peep valve indicated as an accessory to provide positive and expiratory pressure breathing for Cpap and Ventilators.
Two different male ISO inlets 20 and 30 mm.
Pressure range 0 to 20 cmH2O as standard design
Special pressures on demand up to 40 cmH20 for portable alveolar recruitment procedure.

*Válvula Peep portátil. Está indicada como accesorio para proporcionar respiración con presión positiva y espiratoria para Cpap y ventiladores.Dos entradas ISO macho diferentes de 20 y 30 mm. Rango de presión de 0 a 20 cm H2O como diseño estándarPresiones especiales bajo demanda de hasta 40 cmH20 para el procedimiento de reclutamiento alveolar.*




| CODE | CONNEXION ISO | MATERIAL | Type | PRESSURE RANGE (cmH20) |
|---|---|---|---|---|
| PEEP.18 | 18 with adaptor | POM, Stainless Steel | I | 5-20 cmH20 |
| PEEP.22 | 22 Male | POM, Stainless Steel | I | 5-20 cmH20 |
| PEEP.30 | 30 Male | POM, Stainless Steel | I | 5-20 cmH20 |

Bajo demanda se pueden sumbinistrar rangos de presión especiales (0-40 cmH2O).

On demand special pressure ranges (0-40 cmH2O) can be supplied.

## 100% MADE IN SPAIN - EUROPE AND US PATENTED

## FEATURES

- **A** Adjustable pressure **Presión ajustable**
- **B** Non Magnetic Stainless Steel **Acero Inoxidable No Magnético**
- **D** Different Connections **Connexiones Varias**
- **E** Ergonomic Handwheel **Pomo de ajuste ergonomico**
- **F** Operating temperature: 5ºC to 40ºC **Temperatura de trabajo: 5ºC hasta 40ºC**
- **G** Single Package **Unidades Individuales**
- **I** Cpap/Respirator/resuscitator system **Funciona con Cpap y Respiradores y Resuciiadores**

GOBIERNO DE ESPAÑA MINISTERIO DE INDUSTRIA, COMERCIO Y TURISMO

**Proyecto financiado por el Ministerio de Industria, Comercio y Turismo**

REDFLUID

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Barcelona, Spain
ESB58062977

# EU Declaration of Conformity

| | |
|---|---|
| **Manufacturers Name:** | REDFLUID SL |
| **SRN (Single Registration Number):** | |
| **Manufacturers Address:** | CARRER FOC 5, 08227 TERRASSA (BARCELONA), SPAIN |
| **Name of the Device (s):** | ADJUSTABLE 0-20 mmH2O PEEP VALVE MALE INLET REUSABLE |
| **Product code:** | PEEP18, PEEP22, PEEP30 |
| **Classification:** | I. Rule II. Annex VIII MDR 2017/745 |
| **Compliance with standards:** | EN ISO 13485:2016/AC:2018. EN ISO 14971:2012. |
| **Conformity assessment route:** | REDFLUID uses the following procedures for the CE-labeling of their products according the Regulation MDR 2017/745 and amended by Regulation EU 2020/561:<br><br>Class I : EU Declaration of Conformity according to article 19 and annex IV |

This declaration of conformity is issued under the sole responsibility of REDFLUID. We hereby declare that he medical device(s) specified above meet the provision of the Regulation (EU) MDR 2017/745 and emended by Regulation EU 2020/561 for medical devices. This declaration is supported by the Quality System approval to ISO 13485 issued by IMQ.
All supporting documentation is retained at the premises of the manufacturer.

Signature:

Enric Palau
Director
info@redfluid.es

Place and date (dd.mm.yyyy) of issue:

Terrassa, Barcelona, Spain. 22/12/2020

| Reference number | Description |
|---|---|
| PEEP.18 | Adjustable 0-20 cmH2OPeep Valve Reusable Male inlet 18 |
| PEEP.22 | Adjustable 0-20 cmH2OPeep Valve Reusable Male inlet 22 |
| PEEP.30 | Adjustable 0-20 cmH2OPeep Valve Reusable Male inlet 30 |

PEEP VALVE GMDN CODE: 14337, SRC UDI-DI Pending EUDAMED implementation

www.imq.it

CISQ is a member of IQNet
THE INTERNATIONAL CERTIFICATION NETWORK
www.iqnet-certification.com

*IQNet, the association of the world's first class certification bodies, is the largest provider of management System Certification in the world. IQNet is composed of more than 30 bodies and counts over 150 subsidiaries all over the globe.*

# CERTIFICATE N.
# *CERTIFICADO N.* **0104.2021**

WE HEREBY CERTIFY THAT THE MANAGEMENT SYSTEM OPERATED BY
*CERTIFICAMOS QUE EL SISTEMA DE GESTIÓN DE*

## REDFLUID, S.L.

C/ FOC 5 - 08227 TERRASSA (BARCELONA) SPAIN

*OPERATIVE UNITS / INSTALACIÓN DE*

C/ FOC 5 - 08227 TERRASSA (BARCELONA) SPAIN

*IS IN COMPLIANCE WITH THE STANDARD / REÚNE LOS REQUISITOS DE LA NORMA*

## ISO 13485:2016

*FOR THE FOLLOWING ACTIVITIES* / PARA LAS SIGUIENTES ACTIVIDADES

Gestión de la fabricación, ensamblado, venta y distribución de válvulas manuales peeps
*Manufacturing management, assembly, sales and distribution of manual peep valves*

*Further clarifications regarding the applicability of ISO 13485:2016 requirements may be obtained by consulting the organization*
*Cualquier aclaración adicional relativa a la aplicación de la norma ISO 13485:2016, puede obtenerse consultando a la organización*

*THE USE AND THE VALIDITY OF THE CERTIFICATE SHALL SATISFY THE REQUIREMENTS OF THE RULES FOR CERTIFICATION OF MANAGEMENT SYSTEMS*
*EL PRESENTE CERTIFICADO ESTÁ SUJETO AL RESPETO DEL REGLAMENTO PARA LA CERTIFICACIÓN DE LOS SISTEMAS DE GESTIÓN*

| **DATE:** | FIRST CERTIFICATION<br>*PRIMERA CERTIFICACIÓN* | CURRENT ISSUE<br>*EMISION ACTUAL* | EXPIRY<br>*VÁLIDO HASTA* |
|---|---|---|---|
| | 2021-01-29 | 2021-01-29 | 2024-01-28 |

IMQ S.p.A. - VIA QUINTILIANO, 43 - 20138 MILANO ITALY
Management Systems Division - Flavio Ornago

ACCREDIA
L'ENTE ITALIANO DI ACCREDITAMENTO
SGQ N° 005 A
Membro degli Accordi di Mutuo Riconoscimento EA, IAF e ILAC
*Signatory of EA, IAF and ILAC Mutual Recognition Agreements*

The validity of the certificate is submitted to annual audit and a reassessment of the entire management System within three years
*La validez del certificado está sujeta a auditorías anuales y a la recercertificación completa del Sistema de Gestión con una periocidad trienal*

IMQ
Organismo di Certificazione Federato CISQ
www.imq.it

FEDERAZIONE CISQ
www.cisq.com
CISQ è la Federazione Italiana di Organismi di Certificazione dei sistemi di gestione aziendale.
*CISQ is the Italian Federation of management system Certification Bodies.*

# COVID-19 Medical Device Authorization for Importation or Sale

# Autorisation d'importation ou de mise en vente d'un instrument médical relatif au COVID-19

**Authorization Reference Number :** 315940 **Numéro de référence de l'autorisation**

**Issue Date:** 2020-05-25 **Date de délivrance:**

**Device Class/Classe de l'instrument : 2**

Pursuant to section 5 of the Interim Order Respecting the Importation and Sale of Medical Devices for Use in Relation to COVID-19, made by the Minister of Health on March 18, 2020, the medical device listed below is now authorized for sale or importation in Canada.

Each shipment of a COVID-19 medical device that is imported into Canada must be accompanied by a copy of this authorization document. Please ensure to highlight the **Authorization reference number** during the import declaration process to facilitate port entry without any delays.

This authorization is only valid for so long as the Interim Order Respecting the Importation and Sale of Medical Devices for Use in Relation to COVID-19 is in effect.

Conformément à l'article 5 de *l'Arrêté d'urgence concernant l'importation et la vente d'instruments médicaux relatifs au Covid*-19, réalisé par la ministre de la Santé le 18 mars 2020, les instruments indiqués ci-dessous sont présentement autorisés pour la mise en vente ou l'importation au Canada.

Tout envoi d'un instrument médical relatif au COVID-19 doit être accompagné d'une copie de la présente autorisation. Veuillez vous assurez de souligner le **numéro de référence de l'autorisation** durant le processus de déclaration d'importation pour faciliter l'entrée sans délais aux points de contrôle frontalier.

Cette autorisation est uniquement valide tant que *l'Arrêté d'urgence concernant l'importation et la vente d'instruments médicaux relatifs au Covid*-19 est en vigueur, ou l'autorisation est annulée.

**Device Name(s) Nom de l'instrument**

**PEEP VALVE 0-20 CMH20 INLET, PEEP VALVE 0-40 CMH20 INLET**

**Name & Address of Authorization Holder/Nom & adresse du titulaire de l'autorisation**

REDFLUID
FOC 5
TERRASSA, BARCELONA
SPAIN
08227

David Boudreau, ing., Interim Director General, Medical Devices Directorate
Directeur général par intérim, Direction des instruments médicaux

David Bowen

## Components/Parts/Accessories/Devices for this Licence
## Les composantes, parties, accessoires et instruments médicaux pour cette homologation

PEEP VALVE 0-20 CMH20 INLET

**Device ID/No de l'instrument: 1022009**
**Device Identifier / Identificateur de l'instrument**
**(Model/Catalog Detail/No de modèle/Catalogue):**
PEEP.22

PEEP VALVE 0-40 CMH20 INLET

**Device ID/No de l'instrument: 1022010**
**Device Identifier / Identificateur de l'instrument**
**(Model/Catalog Detail/No de modèle/Catalogue):**
REC.22