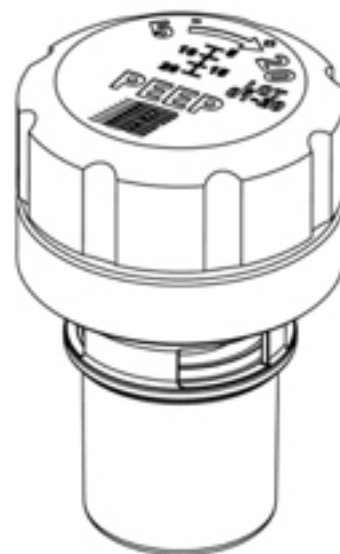


REDFLUID PEEP VALVE

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 cmH₂O for portable alveolar recruitment procedure.
Reusable up to 5 times in autoclave.

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 estándar. Presiones especiales bajo demanda de hasta 40 cmH₂O para el procedimiento de reclutamiento alveolar. Reutilizable hasta 5 veces en autoclave.



CODE	CONNEXION ISO	MATERIAL	Type	PRESSURE RANGE (cmH ₂ O)	STERILIZATION
PEEP.18	18 with adaptor	POM, Stainless Steel	I	5-20 cmH ₂ O	AUTOClave 121°C (5 CICLOS max) ETO
PEEP.22	22 Male	POM, Stainless Steel	I	5-20 cmH ₂ O	AUTOClave 121°C (5 CICLOS max) ETO
PEEP.30	30 Male	POM, Stainless Steel	I	5-20 cmH ₂ O	AUTOClave 121°C (5 CICLOS max) ETO

Bajo demanda se pueden suministrar 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

C Reusable
Reutilizable

D Different Connections
Connexiones Varias

E Ergonomic Handwheel
Pomo de ajuste ergonomico

F Operating temperature: 5°C to 40°C
Temperatura de trabajo: 5°C hasta 40°C

G Single Package
Unidades Individuales

I Cpap/Respirator/resuscitator system
Funciona con Cpap y Respiradores y Resucitadores



Proyecto financiado por el Ministerio
de Industria, Comercio y Turismo



EU Declaration of Conformity

Manufacturers Name: REDFLUID SL

SRN (Single Registration Number): CARRER FOC 5, 08227 TERRASSA (BARCELONA), SPAIN

Manufacturers Address:

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

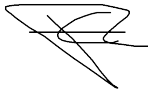
Compliance with standards: EN ISO 13485:2016/AC:2018. EN ISO 14971:2012.

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:

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 the medical device(s) specified above meet the provision of the Regulation (EU) MDR 2017/745 and amended 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 cmH ₂ O PEEP Valve Reusable Male inlet 18
PEEP.22	Adjustable 0-20 cmH ₂ O PEEP Valve Reusable Male inlet 22
PEEP.30	Adjustable 0-20 cmH ₂ O PEEP Valve Reusable Male inlet 30

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



www.imq.it



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 PRIMERA CERTIFICACIÓN	CURRENT ISSUE EMISION ACTUAL	EXPIRY 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



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 recertificación
completa del Sistema de Gestión con una periodicidad trienal



Organismo di Certificazione Federato CISQ
www.imq.it



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.

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.

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.**

Tout envoi d'un instrument médical relatif au COVID-19 doit être accompagné d'une copie de la présente autorisation. **Veillez vous assurer 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.**

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.

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

Application Number:
Numéro de la demande: 315940

Manufacturer ID:
Identificateur du fabricant: 155943



Health Canada
Santé Canada

Medical Devices Directorate
Direction des instruments médicaux

David Bow

Application Number: 315940
Numéro de la demande:

Manufacturer ID: 155943
Identificateur du fabricant:



Components/Parts/Accessories/Devices for this Licence
Les composants, 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