OB500

- Apirator de secretii OB 500
- Dispozitivul este conceput pentru autospeciale medicale si este stationar, nu portabil
- Piston aspirator fara mentenanta
- Putere de aspirare maxima: 800 mbar (80 kPa) ±10%
- Putere de aspirare nominala: 30 LPM la viteza aer liber ±10%
- Timp maxim de aspirare: 60 minute ±10%
- Grad de protectie impotriva infiltratiilor de lichide si solide: IP32d
- Functionare: 12÷15 Vdc
- Control vacuum si unitatea de reglare pot fi instalate pe perete
- Vas colectare autoclavabil OB-J FA 1000 ml cu valva supraplin si filtru de protectie inserat direct in capac, autoclavabil max de 30 ori
- Dimensiuni unitate completa: 175x175x100 mm
- Dimensiuni unitate de reglaj: 53x110x70 mm
- Greutate: max. 2 kg inclusiv cu kitul de instalare
- In conformitate cu toate reglementarile aplicate, Directiva 93/42/EEC si standardele principale de referinta

OSCAR BOSCAROL S.r.l.
Via Enzo Ferrari 29, 39100 Bolzano BZ Italy
VAT Number e Fisc. Code 01458460217
Ph. +39 0471932893 Fax. +39 0257760140
info@boscarol.it - www.boscarol.it

Quality Management

DECLARATION OF CONFORMITY – DICHIARAZIONE DI CONFORMITÁ

We, the manufacturer: *Il produttore:*	**OSCAR BOSCAROL SRL** Via E. Ferrari , 29 – 39100 BOLZANO – ITALY Tel. +39 0471 932893 – Fax. +39 0257760140 Web: www.boscarol.it - Email : info@boscarol.it Certifies EN ISO 13485:2016 – N° Q5 042208 0031 Rev. 00 Certifies UNI EN ISO 9001:2015 – N° 50 100 7289 – R.004 Emission: TÜV–SÜD Product service (CE0123) EC Certificate N° G1 042208 0032 Rev. 00
We declare under our sole responsibility that the device (name):	**MEDICAL SUCTION UNIT**
Dichiariamo sotto nostra responsabilità che il dispositivo (nome):	**ASPIRATORE MEDICALE DI SECRETI**
Type: **Tipo:**	**OB500 STATIONARY SUCTION UNIT**
UMDNS code:	**15-016**
GMDN code:	**63643**
Boscarol code:	**BSU442 – BSU462 – BSU464** **XAS0330 – XAS0331 – XAS0332 – XAS0334** **XAS0336 – XAS0338 – XAS0340**
Devices classification (MDD 93/42/EEC – Annex IX): *Classificazione dispositivo (MDD 93/42/CEE – Allegato IX):*	**Class IIa**
Meets all the provisions of the directive MDD 93/42/EEC and subsequent amendments which apply to it. *Soddisfa tutte le disposizioni della direttiva MDD 93/42/CEE e successivi emendamenti che lo riguardano.*	
Applied harmonised standards, national standards or other normative documents: *Norme armonizzate o nazionali applicate, altri documenti normative applicate:*	**ISO 10079-1** **UNI EN 1789** **IEC 60601-1** **IEC 60601-1-2** **IEC 60601-1-12** **ECE-R10**
Conformity assessment procedure: *Procedimento di valutazione della conformità:*	**MDD93/42/EEC, Annex II (Allegato II)**
Notify body: *Organismo di notifica incaricato della valutazione della conformità:*	**TÜV SÜD PRODUCT SERVICE GmbH** **CE 0123** **Ridlerstrasse 65 – 80339 München - Germany**

Bolzano, 25.08.2020

DIR/RAQ – Quality Manager
Dr. MARCHETTI BENEDETTA

DIR/CEO
BRAZZO DANIELE

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-244.10.08

Product Service

EC Certificate

Full Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

No. G1 042208 0032 Rev. 00

Manufacturer:

OSCAR BOSCAROL S.R.L.
Via Enzo Ferrari, 29
39100 Bolzano (BZ)
ITALY

Facility(ies):

OSCAR BOSCAROL S.R.L.
Via Enzo Ferrari, 29, 39100 Bolzano (BZ), ITALY

Product Category(ies):

Pressure regulators for medical gases, compressed medical gases pipeline set for road ambulances and emergency vehicles, medical suction equipments, defibrillators

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. See also notes overleaf.

Report No.: ITA1311593

Valid from: 2019-07-23
Valid until: 2023-03-01

Date, 2019-07-23

Stefan Preiß
Head of Certification/Notified Body

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany