

SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

COMPRESSED MEDICAL OXYGEN

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Compressed Medical Oxygen Specification

Compressed Medical Oxygen cylinders are supplied to the European Pharmacopoeia (1998) specification which includes:

Compressed Medical Oxygen Purity 99.5%

Maximum Impurity Levels

Carbon Monoxide	5 vpm
Carbon dioxide	300 vpm
Moisture	50 vpm

3. PHARMACEUTICAL FORM

Medicinal gas, compressed.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Medical Oxygen is widely used in clinical practice to:

- provide a basis for most modern anaesthetic techniques including pre and postoperative management.
- restore the tissue oxygen tension towards normal by improving oxygen availability in a wide range of conditions such as:
 - cyanosis of recent origin as a result of cardio-pulmonary disease
 - surgical trauma, chest wounds and rib fracture

- shock, severe haemorrhage and coronary occlusion
 - carbon monoxide poisoning
 - hyperpyrexia
 - major trauma, i.e. road traffic accidents and gunshot wounds
 - in the management of sudden cardiac and respiratory arrest, whether drug induced or traumatic
- aid in the resuscitation of the critically ill, when the circulation is impaired
 - aid in neo-natal resuscitation
 - treat acute severe headache in adults diagnosed with cluster headache

4.2 Posology and method of administration

Medical Oxygen is administered by inhalation through the lungs. The major exception is when a metered supply is fed into the oxygenator of an extracorporeal circulation of a cardio-pulmonary by-pass system.

The need for medicinal oxygen should be determined by obtaining arterial blood gas values and/or by monitoring SpO₂. The inspired oxygen should be titrated when used for long term oxygen therapy in patients with chronic hypoxic respiratory failure. A SaO₂/SpO₂ between 88 and 92% is commonly assessed as adequate in patients with chronic obstructive pulmonary disease (COPD). A too liberal administration can increase the oxygen SaO₂/SpO₂ clearly above the patient's normal range, which may cause respiratory depression because of chemoreceptor insensitivity for CO₂. Blood gases should be monitored to avoid excessive retention of CO₂ in patients with hypercapnia or reduced CO₂- sensitivity, in order to adjust the oxygen therapy

For cluster headache, oxygen should be administered as soon as possible after the onset of the attack, via a non-rebreathing facemask at a flow of 6 to 12 l/min for approximately 15 minutes.

4.3 Contraindications

There are no absolute contraindications to the use of Compressed Medical Oxygen, but the inspired concentration should be limited in the case of premature infants and those patients with chronic bronchitis and emphysema.

4.4 Special warnings and precautions for use

Special care is needed when Medical Oxygen is administered:

- to neonates where the inspired concentration should not exceed 40% because of the risk of retrolenticular fibroplasia

- to elderly chronic bronchitic patients in whom the inspired concentration should only be raised in stages of 1% and probably should not exceed 30%
- in hyperbaric chambers in the management of conditions such as carbon monoxide poisoning, anaerobic infections and acute ischaemic disease. Convulsions may occur at 3 bar (g) after a few hours.

Careful monitoring of oxygen levels on the breath, blood and tissue is required to ensure that appropriate concentrations are not exceeded.

In patients with reduced sensitivity for carbon dioxide pressure in arterial blood, high concentrations of oxygen may cause, respiratory depression subsequently causing carbon dioxide retention (hypercapnia), which in extreme cases can lead to carbon dioxide narcosis.

Where the patient has been exposed to agents which are toxic to the lungs, such as Paraquat, the use of gases containing more than 21% oxygen should be avoided.

Compressed Medical Oxygen is non flammable but strongly supports combustion and should not be used near sources of ignition.

Compressed Medical Oxygen Cylinders should be set up and tested before placing near the patient. Do not place the cylinder on the patient's bed unless there is no suitable alternative for retaining the cylinder.

Smoking should be prohibited when using Compressed Medical Oxygen.

Under no circumstances should oils or grease be used to lubricate any part of the Compressed Medical Oxygen cylinder or the associated equipment used to deliver the gas to the patient.

Where moisturising creams are required for use with a facemask or in nasal passages, oil based creams should not be used.

Check that hands are clean and free from any oils or grease.

Where alcohol gels are used to control microbiological cross-contamination ensure that all alcohol has evaporated before handling Compressed Medical Oxygen cylinders or equipment.

4.5 Interaction with other medicinal products and other forms of interaction

The use of higher levels of oxygen can increase the risk of pulmonary toxicity in patients who have been administered Bleomycin, Amiodarone and Nitrofurantoin or similar antibiotics. In these cases oxygen should be administered with caution and at levels kept as low as possible.

4.6 Pregnancy and Lactation

Compressed Medical Oxygen does not adversely affect pregnancy and lactation.

4.7 Effects on Ability to Drive and Use Machines

In normal circumstances, Compressed Medical Oxygen does not interfere with the conscious level but patients who require continuous Oxygen support are obviously not fit either to drive or to operate machinery.

4.8 Undesirable effects

Compressed Medical Oxygen toxicity can occur as manifested by:

- retrolenticular fibroplasia in premature infants exposed to oxygen concentrations greater than 40%
- convulsions appear after a few hours exposure to Medical Oxygen at pressures above 3 bar(g)
- retrosternal soreness associated with coughing and breathing difficulties, made worse by smoking and exposure to cold air after breathing pure Medical Oxygen at atmospheric pressure for several hours.

The most serious side effects that may occur are severe difficulty in breathing, so called respiratory distress syndrome. Too liberal oxygen administration may also cause respiratory depression in susceptible patients with reduced chemoreceptor sensitivity as seen in e.g. some patients with chronic obstructive pulmonary disease (COPD) causing hypercapnia (frequency not known).

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via The Yellow Card System www.mhra.gov.uk/yellowcard.

4.9 Overdose

Overdose effects for Compressed Medical Oxygen are as detailed in 'Undesirable Effects'.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

The characteristics of Compressed Medical Oxygen are:

Odourless, colourless gas

Molecular weight	32
Boiling point	-183.1°C (at 1 bar (g))
Density	1.355 kg/m ³ (at 15°C)

Oxygen is present in the atmosphere at 21% and is an absolute necessity for life.

The basal Oxygen consumption in man is about 250ml/min for a body surface of 1.8m². It is reduced by about 10% during anaesthesia and natural sleep and by about 50% for a 10°C fall in body temperature.

Alveolar air contains about 14% Oxygen (105mm Hg) and the arterial blood has an Oxygen tension of 97mm Hg. The difference, known as the alveolar-arterial Oxygen tension gradient, increases with age. The difference may be as great as 30mm Hg in a healthy, elderly individual.

Oxygen in the blood is mostly combined with haemoglobin. 1.34ml per 9ml to give a maximum capacity of 20ml per 100ml of blood. A small amount, 0.3ml, exists in solution in the same volume of blood.

The concept of Oxygen availability first described by Richards in 1943 and later elaborated by Freeman and Nunn has been used to quantify the amount of Oxygen available to the body. It can be expressed as the product of the cardiac output and the Oxygen content of the blood.

Available Oxygen is calculated by: (cardiac output) x Hb conc x 1.34 x (% saturation)

Substituting normal values for Available Oxygen the amount is:

Available Oxygen: ((5000ml) 15/100 x 1.34 x 95/100) = 950ml

The average healthy individual with a basal Oxygen consumption has no more than four minutes supply of Oxygen in the blood.

5.2 Pharmacokinetic Properties

The uptake of Compressed Medical Oxygen by the blood in the lungs and discharge to the tissues is determined by the Oxygen dissociation curve. The characteristic sigmoid shape ensures that, at tensions between 40 and 15mm Hg the Oxygen carried in the blood from the lungs can be readily given up to the tissues.

The uptake from the lungs is rapid, because blood flow through the capillaries, where exchange takes place, occurs in about 0.5 seconds. The uptake of Oxygen is favoured by the simultaneous loss of carbon dioxide which is then excreted in the expired air. Conversely the entry of carbon dioxide into the blood from the tissues facilitates Oxygen transfer to the cells.

At rest, mixed venous blood returning to the lungs contains 13-14ml of Oxygen per 100ml, but with severe exercise, the Oxygen content may fall to 3-4ml. In very active tissue, almost complete extraction occurs.

5.3 Preclinical Safety Data

None stated

6. PHARMACEUTICAL PARTICULARS

6.1 List of Excipients

None.

6.2 Incompatibilities

Compressed Medical Oxygen strongly supports combustion and will cause substances to burn vigorously, including some materials that will not normally burn in air. It is highly dangerous in the presence of oils, greases, tarry substances and many plastics due to the risk of spontaneous combustion in the presence of Medical Oxygen in relatively high concentrations.

6.3 Shelf-Life

36 months

6.4 Special precautions for storage

Compressed Medical Oxygen cylinders should be:

- stored under cover, preferably inside, kept dry and clean, and not subjected to extremes of heat or cold and away from combustible material.
- stored separately from industrial and other non-medical cylinders.
- stored to maintain separation between full and empty cylinders.
- used in strict rotation so that cylinders with the earliest expiry date are used first.
- stored separately from other medical cylinders within the store
- F size cylinders and larger should be stored vertically. E size cylinders and smaller should be stored horizontally. As AZ, CD, DD, ZD and IQD cylinders have flat bottoms, they may be stored vertically. Cylinders stored vertically should be secured to prevent them from falling over and causing injury.

Warning notices prohibiting smoking and naked lights must be posted clearly in the cylinder storage area and the Emergency Services should be advised of the location of the cylinder store.

Care is needed when handling and using Compressed Medical Oxygen cylinders.

6.5 Nature and contents of container

A summary of Compressed Medical Oxygen cylinders, their size and construction, type of valve fitted and valve outlet pressure is detailed below:

Cylinder Details				Valve details		
Size	Gas Content (Litres)	Water Capacity (Litres)	Material of Construction	Valve Type	Filling Port	Nominal Valve Outlet Pressure Bar(g)
AZ	170	1.2	Aluminium	Non Regulated Pin Index ISO 407 (Oxygen)		137
ZA	300	1	Aluminium (Carbon Fibre hoop wrapped)	Integral Regulated	ISO 5145 (Oxygen)	4
D	340	2.32	Steel	Non Regulated Pin Index ISO 407 (Oxygen)		137
CD	460	2	Aluminium (Carbon fibre hoop wrapped)	Integral Regulated	ISO 5145 (Oxygen)	4

Cylinder Details				Valve details	
Size	Gas Content (Litres)	Water Capacity (Litres)	Material of Construction	Valve Type Filling Port Outlet Connections Outlet Flowrates	Nominal Valve Outlet Pressure Bar(g)
				Outlet (1) 6 mm Fir Tree Flowrate 1 - 15 litres/min Outlet (2) BS 5682 Schrader Flowrate 40 litres/min (max)	
DD	460	2	Aluminium (Carbon Fibre hoop wrapped)	Valve Type Integral Regulated Filling Port ISO 5145 (Oxygen) Outlet 6 mm Fir Tree Flowrate 2, 4 litres/min	4
IQD	460	2	Aluminium Carbon Fibre hoop wrapped))	Valve Type Integral Regulated Filling Port ISO 5145 (Oxygen) Outlet (1) 6 mm Fir Tree Flowrate 0.5 - 15 litres/min Outlet (2) BS 5682 Schrader Flowrate 40 litres/min (max)	4.5
ZD	605	2	Aluminium (Carbon Fibre hoop wrapped)	Valve Type Integral Regulated Filling Port ISO 5145 (Oxygen) Outlet (1) 6 mm Fir Tree Flowrate 1 - 15 litres/min	4

Cylinder Details				Valve details	
Size	Gas Content (Litres)	Water Capacity (Litres)	Material of Construction	Valve Type Filling Port Outlet Connections Outlet Flowrates	Nominal Valve Outlet Pressure Bar(g)
				Outlet (2) Flowrate BS 5682 Schrader 40 litres/min (max)	
E	680	4.68	Steel	Valve Type Outlet Non Regulated Pin Index ISO 407 (Oxygen)	137
F	1360	9.43	Steel	Valve Type Outlet RPV Non Regulated BS 341 No 3 Top Outlet	137
AF	1360	9.43	Steel	Valve Type Outlet RPV Non Regulated BS 341 No 3 Top Outlet	137
DF	1360	9.43	Steel	Valve Type Filling Port Outlet Flowrate Integral Regulated ISO 5145 (Oxygen) 6 mm Fir Tree 2, 4 litres/min	4
IQX	2300	10	Steel	Valve Type Filling Port Integral Regulated ISO 5145 (Oxygen)	4.5

Cylinder Details				Valve details	
Size	Gas Content (Litres)	Water Capacity (Litres)	Material of Construction	Valve Type Filling Port Outlet Connections Outlet Flowrates	Nominal Valve Outlet Pressure Bar(g)
				Outlet (1) 6 mm Fir Tree Flowrate 0.5 - 15 litres/min Outlet (2) BS 5682 Schrader Flowrate 40 litres/min (max)	
HX	2300	10	Steel	Valve Type Integral Regulated Filling Port ISO 5145 (Oxygen) Outlet (1) 6 mm Fir Tree Flowrate 1 - 15 litres/min Outlet (2) BS 5682 Schrader Flowrate 40 litres/min (max)	4
ZH	2400	8	Steel (Carbon Fibre hoop wrapped)	Valve Type Integral Regulated Filling Port ISO 5145 (Oxygen) Outlet (1) 6 mm Fir Tree Flowrate 1 - 15 litres/min Outlet (2) BS 5682 Schrader Flowrate 40 litres/min (max)	4

Cylinder Details				Valve details	
Size	Gas Content (Litres)	Water Capacity (Litres)	Material of Construction	Valve Type Filling Port Outlet Connections Outlet Flowrates	Nominal Valve Outlet Pressure Bar(g)
ZX	3040	10	Steel (Carbon Fibre hoop wrapped)	Valve Type: Integral Regulated Filling Port: ISO 5145 (Oxygen) Outlet (1): 6 mm Fir Tree Flowrate: 1 - 15 litres/min Outlet (2): BS 5682 Schrader Flowrate: 40 litres/min (max)	4
G	3400	23.6	Steel	Valve Type: RPV Non Regulated Outlet: BS 341 No 3 Top Outlet	137
J	6800	47.2	Steel	Valve Type: Non Regulated Outlet: Pin Index Pin Index ISO 407 (Oxygen)	137
W	11300	46.6	Steel	Valve Type: RPV Non Regulated Outlet: ISO 5145 (Oxygen)	230

Cylinders

All cylinders used for the storage of Compressed Medical Oxygen are manufactured from either high tensile steel or aluminium.

The AZ, D, E, F, AF, DF, G and J size cylinders are designed with working pressure of at least 137 bar(g)

The CD, DD, IQD, IQX, HX and W size cylinders are designed with a maximum working pressure of 230 bar (g).

The ZA, ZD, ZH and ZX size cylinder are designed with a maximum working pressure of 300 bar(g).

The CD, DD, ZD, IQD, ZH and ZX cylinders are carbon fibre hoop wrapped to increase the working pressure of the aluminium or steel cylinder liner and reduce the

weight of the cylinder package. The carbon fibre windings are protected using a PVC sleeve.

The ZA cylinder is a carbon fibre full wrapped cylinder, with the carbon fibre wrapped over the shoulder and base of the cylinder liner to reduce the cylinder weight further.

The ZA cylinder is gel coated to protect the windings.



of the shoulders of Compressed Medical Oxygen cylinders is white
of the cylinder body is white (RAL 9010). Cylinders also carry the
e body of the cylinder.

For a limited period, cylinders may have black bodies. These cylinders do not have the name oxygen on the body of the cylinder.

The programme to convert all Compressed Medical Oxygen cylinders to white bodies will be completed by 2027.

Cylinder Valves

Compressed Medical Oxygen cylinders are supplied with two main types of cylinder valves, dependent upon the cylinder filling pressure and the type of application.

Conventional cylinder valves are fitted to AZ, D, E, F, AF, G and J cylinders which are designed to be used with a pressure regulator. All of these cylinders are fitted with valves with outlet connections that conform to either ISO 407 (pin index) or BS 341 (5/8" BSP F) and are filled to 137 bar (g). The cylinder valves are constructed from high tensile brass with a steel spindle fitted with a Nylon 6.6 insert.

The side outlet hand wheel valve fitted to W cylinders has an ISO 5145 product specific valve outlet. The valve design incorporates a residual pressure device to prevent the cylinder from being fully emptied and prevent the cylinder from being contaminated should the valve be left open. The valve is constructed from brass and is fitted with a brass spindle with a Nylon 6.6 insert. The residual pressure device is fitted with EDPM O-ring seals.

ZA, ZD, CD, DD, DF, ZH, HX, and ZX cylinders are fitted with valves that have an integral pressure regulator, with an outlet pressure of 4 bar(g). These cylinder valves are fitted with an ISO 5145 product specific filling connection.

They have a product specific BS 5682 Schrader outlet connection and/or a standard 6mm fir tree outlet.

Integral cylinder valves are constructed from high tensile brass with a steel spindle fitted with a Nylon 6.6 insert.

The IQD and IQX package utilises the LIV IQ medical device system manufactured by Rotarex. The device incorporates a valve with an integral pressure regulator with

an outlet pressure of 4.5 bar(g) to a 2 litre (IQD) or 10 litre (IQX) cylinder. These regulated valves are fitted with an ISO 5145 product specific filling connection and a product specific BS 5682 Schrader outlet connection and a standard 6mm fir tree outlet. The valve is constructed from high tensile brass with a steel spindle fitted with a Nylon 6.6 insert.

In addition, the valve has an electronic pressure gauge and display providing real time information regarding flowrate, length of time remaining for therapy (at the current flowrate) as well as providing visual and audible alarms / warnings for the user.

The non-metallic O-rings and valve seat materials used in the internal construction of the valves are compatible with Medical Oxygen and compliant with the requirements of ISO 15001. The standard specifies that the accepted material will not produce toxic fumes should an ignition occur within the valve.

6.6 Special precautions for disposal and other handling

All personnel handling Compressed Medical Oxygen cylinders should have adequate knowledge of:

- physical properties of Oxygen
- correct operating procedures for the cylinder
- precautions and actions to be taken in the event of an emergency.

Preparation for Use

Cylinders used with a pressure regulator

Sizes AZ, D, E, F, AF, G, J and W

To prepare the cylinder for use, before placing near the patient:

- remove the tamper evident seal and the valve outlet protection cap.
- for cylinders which have a replaceable cap, retain the cap for refitting after use
- ensure the batch label fitted to the cylinder is not removed or discarded
- ensure that an appropriate Compressed Medical Oxygen regulator or manifold tailpipe is selected for connection to the cylinder.
- ensure the connecting face on the regulator is clean and the sealing washer fitted is in good condition.
- connect the regulator or tailpipe, using moderate force only and where appropriate connect the tubing to the regulator / flowmeter outlet. Only the appropriate regulator should be used for the particular gas concerned.
- open the cylinder valve slowly and check for any leaks.

Cylinders with an integral regulated valve

Sizes ZA, ZD, CD, DD, IQD, DF, ZH, HX, ZX and IQX

Set up and test the cylinder prior to use and before placing the cylinder near the patient.

To set up the cylinder prior to use:

- check the cylinder label to ensure it is the correct gas for the patient's therapy
- check the cylinder batch label to ensure the gas is within expiry date
- check the cylinder valve contents gauge to ensure that the cylinder contains enough gas for patient treatment. For the IQD and IQX check the cylinder contents indicator on the electronic display to ensure that there is sufficient gas contents in the cylinder. Full IQX and IQD cylinders will have a diamond on the display which also acts as a tamper evident symbol.

- ensure the flow selector on top of the device is set to zero and the hand wheel is turned off before connecting equipment
- remove the cylinder valve handwheel cover (tamper evident seal) over the cylinder valve handwheel (first use only) and open the valve outlet cover. Do not remove the outlet cover as it should be closed after use.
- With the cylinder valve handwheel closed, check the integral regulator is empty by selecting a flow and wait for the flow to stop. Return the flow selector to zero. If the flow does not stop return the flow selector to zero and segregate the cylinder to return to BOC.
- With the outlets facing away from yourself and/or the patient, open the cylinder valve handwheel slowly by turning it anti-clockwise.
- Select 5 lpm, using the flow selector and check that gas flows for at least 10 seconds.
- Close the cylinder valve handwheel and when the flow stops return the flow selector to zero.

Having set up the cylinder and confirmed that the gas flows correctly, the cylinder can be prepared for patient's use. Under no circumstances should the cylinder be set up (or prepared) on the patient's bed.

To prepare the cylinder for patient use

- If the cylinder has been previously used (the tamper evident seal/symbol will not be present) check the valve contents gauge to ensure there is sufficient gas for the patient treatment. Where the contents gauge needle is in the red section, consider replacing the cylinder to ensure there is sufficient gas available for use.
- Check the gas is correct for the patient and the gas is within the expiry date on the batch label
- Open the outlet cover and either connect 6 mm tubing to the fir tree outlet or insert the BS 5682 Schrader probe into the pressure outlet
- With the outlets facing away from yourself and/or the patient, open the cylinder valve slowly and check for any leaks. If using fir tree outlet select flow.
- Avoid placing the cylinder in the patient's bed. It is preferable to use a cylinder holder to keep the cylinder upright and secure when in use

Leaks

Cylinders used with a pressure regulator

Sizes AZ, D, E, F, AF, G, J and W

Having connected the regulator or manifold yoke/connector to the cylinder check the connections for leaks using the following procedure:

- should leaks occur this will usually be evident by a hissing noise.
- if a leak occurs between the valve outlet and the regulator or manifold yoke/connector, depressurise and remove the fitting and fit an approved replacement sealing washer. Reconnect the fitting to the valve with moderate force only, fitting a replacement regulator or manifold tailpipe as required.
- sealing or jointing compounds must never be used to cure a leak.
- never use excessive force when connecting equipment to cylinders.
- if leak persists, label cylinder and return to BOC

Cylinders with an integral regulated valve

Sizes ZA, ZD, CD, DD, IQD, DF, ZH, IQX, HX, and ZX

Check the connection for leaks using the following procedure:

- Should leaks occur this will usually be evident by a hissing noise.
- Close valve, remove connection, check and refit.
- Never use excessive force when connecting equipment to cylinders
- If leak persists, label cylinder and return to BOC

Use of Cylinders

When Compressed Medical Oxygen cylinders are in use ensure that they are:

- only used for medicinal purposes.
- turned off, when not in use, using only moderate force to close the valve
- only moved with the appropriate size and type of trolley or handling device.
- handled with care and not knocked violently or allowed to fall.
- used with an appropriately designed cylinder support to hold the cylinder whilst in use adjacent to the patient. Do not place the cylinder on the patient's bed unless there is no suitable alternative for retaining the cylinder
- where the cylinder is being used in accident and emergency/ambulance situations the cylinder should only be placed on the trolley after the valve has been turned on and the flow rate set.
- not allowed to have any markings, labels or batch labels obscured or removed
- not used in the vicinity of persons smoking or near naked lights.

After use

Cylinders used with a pressure regulator

Sizes AZ, D, E, F, AF, G, J and W

When the Compressed Medical Oxygen cylinders are empty ensure that the:

- cylinder valve is closed using moderate force only and the pressure in the regulator or tailpipe released.
- valve outlet cap, where fitted, is replaced

Cylinders with an integral regulated valve

Sizes ZA, ZD, CD, DD, DF, ZH, HX, and ZX

When the Compressed Medical Oxygen cylinders are turned off or empty ensure that the:

- cylinder valve is closed slowly using moderate force
- valve is allowed to vent before turning the flow selector to zero
- equipment is disconnected
- valve outlet cap, where fitted, is replaced

Sizes IQD and IQX

When the Compressed Medical Oxygen cylinders are turned off or empty ensure that the:

- flow selector is turned to zero
- cylinder valve is closed slowly using moderate force
- equipment is disconnected
- valve is allowed to vent by selecting a flow
- flow selector is turned to zero again
- valve outlet cap, where fitted, is replaced

Empty cylinders must be returned immediately to an empty cylinder storage area for return to BOC.

7 MARKETING AUTHORISATION HOLDER

BOC Ltd

Forge

43 Church Street West,

Woking,

Surrey,

GU21 6HT,

United Kingdom

8. MARKETING AUTHORISATION NUMBER(S)

PL 00735/5000R

**9. DATE OF FIRST AUTHORISATION / RENEWAL OF THE
AUTHORISATION**

Date First Granted: 01/09/1972

Date of Renewal: 21/07/1997

10 DATE OF REVISION OF THE TEXT

11/11/2025