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MEDICAL GAS CONTROL

WHITE PAPER:

The status of home oxygen service providers under EU regulation and the legal requirement to fit oxygen firebreaks

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Executive Summary

The recent enactment of the new Medical Device Regulations (MDR) makes no change to the status of home oxygen service providers in Europe from that provided by the existing Medical Device Directive (MDD) but it does bring much needed clarity as to their role, responsibilities and liabilities.

The MDR does raise the regulatory bar for medical devices in general and sets a clear direction of travel towards a much more robust regulatory environment.

Both the MDD and MDR are legal acts that apply to all economic operators in the supply chain, including home oxygen service providers. This is not widely appreciated by providers.

The question of whether home oxygen service providers remain as ***distributors*** under the regulations or take on the significant regulatory burden of becoming a ***manufacturer*** is largely down to their understanding and following of the rules, which are clearly set out in both regulations.

One important rule is that ***distributors*** must use equipment as intended by the ***manufacturer*** in accordance with their instructions. By not following an oxygen concentrator manufacturer's instruction to fit a firebreak close to the patient, which must stop the flow of oxygen in the event of a fire, invalidates the oxygen concentrators CE mark and changes the status of the home oxygen provider from a ***distributor*** to a ***manufacturer***.

Underpinning medical device regulation is the fundamental principle within risk management of adopting solutions that '***reduce risk as far as possible***' in line with the '***state of the art***'. Firebreaks are the '***state of the art***' because they are required under ISO 8359:2009+A1:2012, the EU harmonised type standard for oxygen concentrators. Not fitting a firebreak could never be considered as meeting the '***reducing risk as far as possible***' test.

Fires in home oxygen installations occur routinely and lead to serious injury and sometimes death, so the risk is recognised and real.

Given the requirement to adopt solutions that ***reduce risk as far as possible*** in line with the ***state of the art***, the fitting of firebreaks is a requirement irrespective of the oxygen source, be it concentrator, liquid oxygen Dewar or gas cylinder.

The regulations, as currently enacted under the Medical Device Directive and as strengthened by the recently enacted Medical Device Regulation, require that oxygen firebreaks are fitted in all home oxygen installations across Europe.

Background

The new Medical Device Regulation[1] (MDR) was enacted on the 26th May 2017 ushering in stronger regulatory requirements for all economic operators in the medical device supply chain in Europe as well as much needed clarity on the roles, responsibilities and liabilities of all the parties involved in putting medical devices into service.

The Medical Device Directive[2] (MDD), which is transposed into national law in each member state, already places legal obligations on ***manufacturers, authorised representatives, importers*** and ***distributors***[3]. However, many home oxygen service providers are unaware that they are subject to this directive or indeed appreciate that they fall under its definition of ***distributor*** with incumbent responsibilities. This is predominantly because a) ***distributors*** in the supply chain have historically rarely been subject to scrutiny from Notified Bodies or Competent Authorities, and b) much of the context for the MDD is defined in a separate guidance document referred to as the '***Blue Guide***' on the ***implementation of EU product rules 2016***[4]. The Blue Guide describes how individual product directives fit into the new approach adopted in 2008 by the European Union known as the New Legislative Framework (NLF).

The position has become a lot clearer with the introduction of the MDR, which effectively combines the MDD with the relevant sections of the Blue Guide in line with the NLF. The MDR is subject to a transition period of three years. During this period either the MDD or the MDR must be applied.

The new Medical Device Regulation also considerably strengthens the regulations around medical devices in line with the determination by the European Commission to raise levels of safety in the sector following some well-published device failings, notably the PIP breast implant scandal[5].

Often the question asked of BPR Medical by home oxygen service providers is whether the fitting of firebreaks is 'mandated'. The aim of this white paper is to provide further clarity on the specific roles and requirements of a home oxygen service provider under current medical device regulation in Europe and answer the question as to whether it is a legal requirement to fit oxygen firebreaks in home oxygen installations.

The Status of Home Oxygen Service Providers Under Current Medical Device Regulations

The Blue Guide and the MDR define four categories of economic operator: ***manufacturer, authorised representative, importer*** and ***distributor***. Each category of economic operator has a different role and responsibilities under the regulations with the most onerous responsibilities falling on the medical device manufacturer. All economic operators are subject to some level of scrutiny from the surveillance authorities in each member country.

The additional requirements of being an ***importer*** and/or an ***authorised representative*** are not within the scope of this white paper and are not addressed by it, although of course they cannot be ignored by economic operators.

Home oxygen service providers are clearly economic operators, the key question is whether a home oxygen service provider is a ***distributor*** or a ***manufacturer*** under the regulations.

[1] Council Regulation (EU) 2017/745 on medical devices
[2] Council Directive 93/42/EEC concerning medical devices
[3] The four categories of economic operator are provided in the Blue Guide
[4] Blue Guide - 2016/C 272/01
[5] Poly Implant Prosthesis (PIP) silicone implant

If an economic operator is putting a device into service in the EU for its intended purpose, using accessories provided or recommended by the manufacturer, in accordance with the manufacturer's instructions and under the manufacturer's name, then the economic operator is a ***distributor***.

However, this is not the typical home oxygen provider business model, which is based upon the home oxygen provider purchasing an oxygen concentrator (or other oxygen source) and assembling this with a combination of accessories (e.g. oxygen tubing, nasal cannula, connectors, humidifier, etc.) from various sources.

If the accessories selected are not those explicitly provided or recommended by the manufacturer of the oxygen concentrator, then it follows that they have not been able to verify compatibility with their equipment. In the case of an oxygen concentrator, the combination of accessories assembled can impact on the performance of the device and increase risk. For example, using tubing and accessories that are unduly restrictive to oxygen flow may adversely affect the accuracy of the delivered oxygen prescription. Indeed, for this reason, oxygen concentrator manufacturers include warnings in their instructions for use (IFU) highlighting the need to use only their accessories. This is an important point picked up in the latest version of the oxygen concentrator type standard EN ISO 80601-2-69:2014, which includes significant new clauses requiring oxygen concentrator manufacturers to make clear in their IFU what combinations of accessories are acceptable with their device. Although this standard is not yet harmonised within Europe, it is likely to be harmonised soon and anyway points to the state of the art.

Where the home oxygen provider chooses not to use only those accessories provided or recommended by the oxygen concentrator manufacturer, the home oxygen provider is taking on the responsibility for that additional risk. In effect, the home oxygen provider is developing a 'system' from different medical devices ('accessories' are medical devices under the regulations) and putting it into service. They become a 'system assembler'. Fortunately, the regulations provide clear guidelines on this matter.

System assemblers fall under the definition of a ***distributor*** under the regulations if (and only if) they follow the rules for assembling medical device systems (discussed later in this paper) and if they do not re-label the system and place it on the market under their own name. The definition of a distributor and the rules for assembling medical device systems are similar in both the MDR and the MDD.

Home Oxygen Service Providers as System Assemblers Under the Regulations

Both the MDD (Article 12) and the MDR (Article 22) have articles covering the activities of ***system assemblers***. These articles specifically provide a means to allow ***system assemblers*** to put together several discrete medical devices into an assembly and put it into service without having to apply all the rules required of a new medical device by a ***manufacturer***. In short, it allows system assemblers to remain as ***distributors*** with fewer responsibilities than a ***manufacturer*** without compromising safety.

Articles 12 and 22 of the MDD and MDR respectively are clear about the rules that ***system assemblers*** must follow, which can be summarised as follows:

1. All devices in the system must be CE marked under the MDD (or MDR)
2. The devices must be compatible when used in accordance with their intended use and in accordance with the ***manufacturer***'s instruction for use
3. The instructions provided with each device for their safe use must be provided with the system or an equivalent safety instruction provided
4. The ***system assembler*** does not put the system into service under their own name and leaves the original CE marking in place for each device.

To comply, ***system assemblers*** are required to make a declaration for each ***system*** type that they assemble confirming the above, which should be available for inspection by the surveillance authority in any member state. Incidentally, the MDR now also requires that each system will have its own unique device identification (UDI), when this part of the regulation is implemented.

If the ***system*** does not meet these rules, then Article 12 of the MDD says that the system becomes a new medical device in its own right and the ***system assembler*** becomes a ***manufacturer*** subject to the full compliance requirements given in Article 11 of the MDD.

Using non-CE marked devices for example or not using CE marked devices per their instructions for use would result in the ***system assembler*** moving status from ***distributor*** to ***manufacturer***, which comes with a very significant regulatory burden and one home oxygen service providers will understandably want to avoid.

The Decision Tree provided in the annex summarises this point.

The Importance of Harmonised Standards

Harmonised standards are those recognised by the EU and published in the ***Official Journal of the European Union***. Conforming to a harmonised type standard is voluntary, but doing so automatically provides a presumption of conformity with the ***Essential Requirements*** for safety and performance required by the MDD and the MDR. It is not the only method of meeting the ***Essential Requirements*** and it is possible to develop an alternative safety argument.

The harmonised type standard for Oxygen Concentrators is EN ISO 8359:2009+AMD1. This type standard includes two requirements around firebreaks, summarised as follows:

1. "The operator-accessible oxygen concentrator outlet shall include a means to prevent the propagation of fire back through the oxygen concentrator outlet in the case that the accessory becomes ignited."
2. "The accessories set-up that delivers gas to the patient from an oxygen concentrator shall include a means to stop the flow of gas towards the patient in the case that the accessory becomes ignited. The means of protection should be located as close to the patient as reasonably practicable."

These requirements to provide additional protection against fire are explicit and directly link, via its Annex ZA, the harmonised type standard EN ISO 8359: 2009+AMD1 with the ***Essential Requirements*** of the MDD and MDR, remembering that the MDD is a legal requirement affecting all economic operators.

EN ISO 8359: 2009+AMD1 was harmonised in January 2015, so all oxygen concentrators placed on the EU market from this date must meet both the above requirements of the type standard, or provide an alternative safety argument, for the manufacturer to legally apply the CE mark. Given that there is no equivalent or alternative safety solution available on the market at present in relation to the protection against the effects of fire, it follows that conformity to the appropriate clauses in the harmonised standard is the only practical approach to conformity with the ***Essential Requirements*** of the MDD.

In practice oxygen concentrator manufacturers do apply the harmonised standard to legally make the device available to the market and typically do this in two ways. The first requirement to prevent the propagation of fire back into the concentrator is typically resolved by making the operator-accessible outlet from metal. This satisfies the first requirement of the standard. It does not however satisfy the second requirement because it neither stops the flow of oxygen nor can it be fitted close to the patient.

Oxygen concentrator manufacturers typically do not provide accessories and therefore cannot control what arrangements of accessory are used for any given patient. Hence, the safety requirement for fitting a firebreak near the patient is added to the oxygen concentrator's IFU so that the requirement for this important risk control measure is communicated down the supply chain to the ***system assembler***. By ensuring that this instruction is in the IFU the concentrator manufacturer is satisfying the second requirement.

It is also worth noting that there is no distinction in the requirement for low risk versus high risk patients (which is impossible to judge anyway) and no economic argument given the very low cost of implementation.

Distributors' Responsibilities

Some home oxygen service providers perceive that they are not subject to the EU regulations, they believe the regulations only affect the device ***manufacturer***, but this is not the case as the Blue Guide and the MDR make clear.

A home oxygen provider acting as a ***distributor*** and putting into service an oxygen concentrator using only the accessories provided or recommended by the oxygen concentrator manufacturer must fit a firebreak to maintain conformity to the ***Essential Requirements*** and the integrity of the CE mark applied by the oxygen concentrator manufacturer.

Similarly, an oxygen service provider acting as a system assembler under Article 12 of the MDD (i.e. using accessories purchased from various sources) can only maintain its status as a ***distributor*** if it follows the ***system assembler*** rules under Article 12, which include following the instructions given by the oxygen concentrator manufacturer.

Another way of putting it, is that the oxygen concentrator manufacturer is relying on the fitting of a firebreak close to the patient to conform to the Essential Requirements and legally apply the CE mark. If the ***distributor*** fails to follow the instruction given by the concentrator manufacturer to fit such a firebreak, then the Essential Requirements are not met and the CE mark is no longer valid.

The regulations are clear that a home oxygen provider acting as a ***distributor*** under the regulations, has a responsibility to act in accordance with the MDD and the Blue Guide or the MDR. The Blue Guide makes clear that a ***distributor*** modifying a product to the extent that compliance with the ***Essential Requirements*** becomes affected, becomes the ***manufacturer***.

The other main responsibilities for a *distributor* are:

- To ensure that the CE mark is correctly applied to each medical device in the system
- To ensure instructions and other safety information are in the correct language for the market
- To act with due care in relation to the applicable requirements [of the MDD or MDR]
- Alert the surveillance authorities when they are aware of non-conformity (vigilance) and act with the manufacturer to remove that non-conformity
- Maintain levels of traceability (received from and provided to)

Risk Management in the Regulations

Risk is defined in risk management as 'the combination of the probability of occurrence of harm and the severity of that harm'. The MDD and the MDR are substantively built on the management of risk by applying a set of challenges that every medical device must meet, referred to as the ***Essential Requirements***. These are generic in nature and given in Annex 1 of both the MDD and the MDR.

The ***Essential Requirements*** enshrine the need 'to reduce risk as far as possible' and follow principles consistent with the 'state of the art'. These two requirements are fundamental tenets of the MDD and MDR regulations.

The previous approach using the principle of reducing risk to As Low As Reasonably Practicable (ALARP principle) as provided for in ISO 14971:2007 – ***Risk management of medical devices***, that might infer a financial consideration into the risk-benefit equation, has been replaced and is no longer applied under the regulations.

In dealing with risk, the regulations define a hierarchy of how risk control measures should be applied. In the first instance risks should be removed or reduced by design. If an unacceptable residual risk remains, then protection measures and/or alarms should be provided. Finally, if neither of the first two options can be applied to successfully mitigate the risk then instructions for use shall advise the user of the remaining or residual risk. Again, this principle is fundamental to the way in which medical devices are designed, manufactured and placed on the market.

A final consideration is that given by BS EN ISO 14971:2012 – ***Risk management for medical devices*** that says that a manufacturer must apply all available control measures even if previous control measures have reduced risk to an 'acceptable level'.

Home oxygen fires are a recognised problem for the industry and continue to occur leading to serious injury and death. The current approach to mitigating this risk is through patient education and warning labels.

Considering the fitting of firebreaks in the context of risk management within the medical device regulations the following applies:

- Firebreaks are a risk control measure that act automatically in the event of a fire (i.e. risk mitigation by design)
- Firebreaks have been available for more than 10 years and are mandated in the UK and Germany. It would be difficult to argue that they are not the current 'state of the art'
- There is currently no effective alternative risk control measure (no alternative safety argument)
- Firebreaks are a specific risk control measure within the harmonised oxygen concentrator type standard (EN ISO 8359:2009+A1:2012).

  The requirement was added to the standard in 2012 by consensus of the ISO technical committee. It is worth noting that the ISO technical committee did not wait for the next natural update of the standard but released it as a specific amendment to the standard, which is indicative of the urgency of their desire to act to protect.
- The requirement in the harmonised standard says that firebreaks 'shall' be fitted in the accessory close to the patient, which automatically makes their fitting 'state of the art'
- Manufacturers are obliged to use ***all*** control measures even if previous control measures have reduced risk to an 'acceptable level'.
- The fitting of a firebreak is a low-cost solution (< €3 for a 4-year Intended Life)

Whilst most oxygen installations use an oxygen concentrator as its source, there are other oxygen source modalities, such as liquid oxygen Dewar's and gas cylinders, that provide a largely equivalent approach to patient care. The ISO type standards for the medical devices used in these modalities have not been updated to require firebreaks to be fitted in the same way that oxygen concentrators have. However, both liquid and cylinder oxygen have large reservoirs of oxygen that offer an additional risk in the event of a fire, beyond that of an oxygen concentrator. Applying the principle of ***reducing the risk as far as possible*** and applying current ***state of the art***, it is evident that firebreaks should also be fitted in home oxygen systems using liquid and gaseous oxygen in cylinders.

Conclusion: Are Firebreaks 'Mandated'?

A home oxygen provider putting an oxygen concentrator into service must fit into the oxygen delivery tubing, close to the patient, a firebreak that stops the flow of oxygen in the event of a fire. Failure to do so invalidates the CE mark applied by the oxygen concentrator manufacturer because there is a reliance by the manufacturer on the provider fitting a firebreak (as instructed in the IFU) in order to meet the Essential Requirements for safety and performance of the MDD or MDR. The Blue Guide makes clear that if a ***distributor*** modifies a product to the extent that compliance with the applicable requirements becomes affected, then they become the ***manufacturer***.

Furthermore, where a home oxygen provider is not using accessories provided or recommended by the manufacturer and purchasing accessories from various sources they assume the responsibility for ensuring that these are compatible. As such, the home oxygen provider becomes a 'system assembler' and must follow the rules in Article 12 of the MDD, which include following the manufacturer's instructions for each device in the system. Once again, failure to follow the rules changes the status of the home oxygen provider from ***distributor*** to ***manufacturer***, with significant regulatory implications.

Underpinning all of this are the fundamental principles of risk management, on which the MDD and MDR are based. These principles require that the solutions adopted ***reduce risk as far as possible*** in line with the ***state of the art***. Firebreaks are a recognised and obligatory requirement of the ISO harmonised type standard for oxygen concentrators, so they represent ***state of the art***. Not fitting a firebreak does not satisfy the requirement for an economic operator to adopt solutions that ***reduce risk as far as possible***.

The reduce risk as far as possible also applies irrespective of the oxygen source, so home oxygen installations using a liquid oxygen Dewar or a gas cylinder equally require the fitting of an oxygen firebreak.

Fires in home oxygen installations occur routinely and lead to serious injury and sometimes death, so the risk is recognised and real.

In our experience of working with home oxygen service providers, few are aware of the full extent of their legal and regulatory responsibilities under the MDD and now the MDR. Many home oxygen service providers we speak to believe that the oxygen concentrator is compliant and there is nothing further for them to do. This paper is intended to dispel this misconception and aims to provide information against which home oxygen service providers can review and consider their status and operational policies.

Further Information

If you would like to know more about oxygen firebreaks or require clarification on any point in this White Paper, then please contact **info@bprmedical.com**.

BPR Medical

BPR Medical is an international leader in the design and manufacturing of medical gas control products. Based in Nottinghamshire, UK, it continues to provide innovative products for acute hospital, emergency and home care applications.

The company has won many awards including a Queen's Award for Innovation in 2012 for its Firesafe product range and is currently the world's leading supplier of oxygen firebreaks in medical applications.

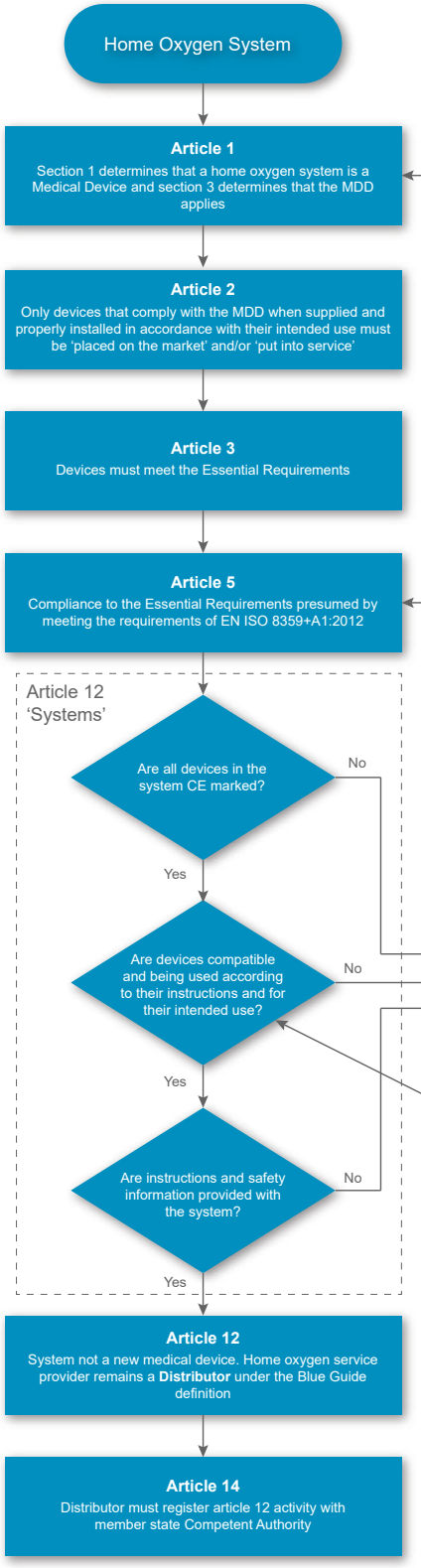
The team specialises in developing successful long-term partnerships with some of the leading medical gas companies and currently exports to 40 different countries. BPR has developed an enviable reputation by delivering on quality at all levels in the business in line with its Zero Defects goal.

Disclaimer

This White Paper and the position it presents is the considered and sincerely held view of BPR Medical Ltd. The position stated is believed to be an accurate representation of the current regulatory position of home oxygen service providers and the requirement to fit firebreaks, which has been developed in conjunction with an independent medical device regulatory professional and our legal advisors. However, BPR Medical makes no claim as to its legal or regulatory accuracy and the reader should not rely on anything contained within it when making commercial or other decisions in relation to its operational policies. BPR Medical strongly recommend that independent legal and regulatory advice is obtained before taking any action. July 2017©

Decision Tree

Home Oxygen Systems under the Medical Device Directive (93/42/EEC)



Note

Devices can only be 'placed on the market' by a Manufacturer or Importer. Distributors can only 'make devices available' and/or 'put into service'.

[Sections 2.2 and 2.3 of the 'Blue Guide' on the implementation of EU product rules 2016 https://ec.europa.eu/docsroom/documents/18027/]

Note relating to Oxygen Concentrators

Amendment 1 of the harmonised standard EN ISO 8359:2009 was published in the OJEU on 16th January 2015. Annex ZA, which provides a cross-reference between requirements of the standard and the Essential Requirements of the Medical Device Directive, was also revised. Compliance with the revised clause 10.3 of EN ISO 8359:2009, which now includes measures to reduce the risk of propagation of fire, corresponds to and provides a presumption of conformity with essential requirements 9.3 and 12.7.4. Unless alternative risk controls that are at least as safe and effective as those specified in the amended standard are applied, the essential requirements are not met.

Note

Manufacturers of oxygen concentrators who 'place on the market' after January 2015 are required to include in the Instructions for Use the requirement that *"accessories (nasal cannula and tubing or mask and tubing) shall be provided with a means to extinguish a tubing fire and isolate the oxygen flow. This should be fitted close to the patient"*. An 'assembler' of a 'system' under Article 12 must follow this instruction or they create a new medical device subject to Article 11 compliance measures.