



Derek Lamb <liquidgands@gmail.com>

Re: Use by dates, put into use by dates or install dates?

1 message

Steve Nixon <steve.nixon@viamed.co.uk>

3 September 2015 at 16:09

To: "Helms, Eleonore" <Eleonore.Helms@honeywell.com>

Cc: Jessica Wagner <jessica.wagner@honeywell.com>, Derek Lamb <derek.lamb@viamed.co.uk>

Thank you Eleonore.

As the medical oxygen sensors that you manufacture for us are on an Own Brand Label basis, we will and have to follow suit with your decisions and labelling designs. Once prepared can you please let me have copy of your updated Envitec master copy labelling and a copy of the updated Viamed labels.

Regards

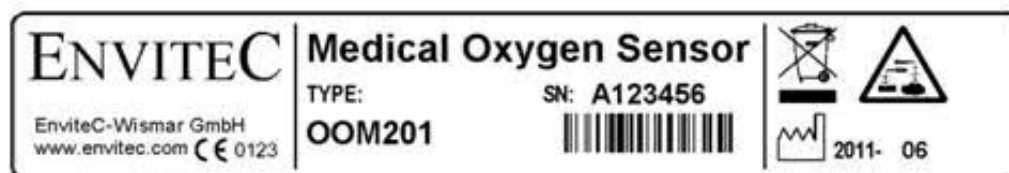
Steve

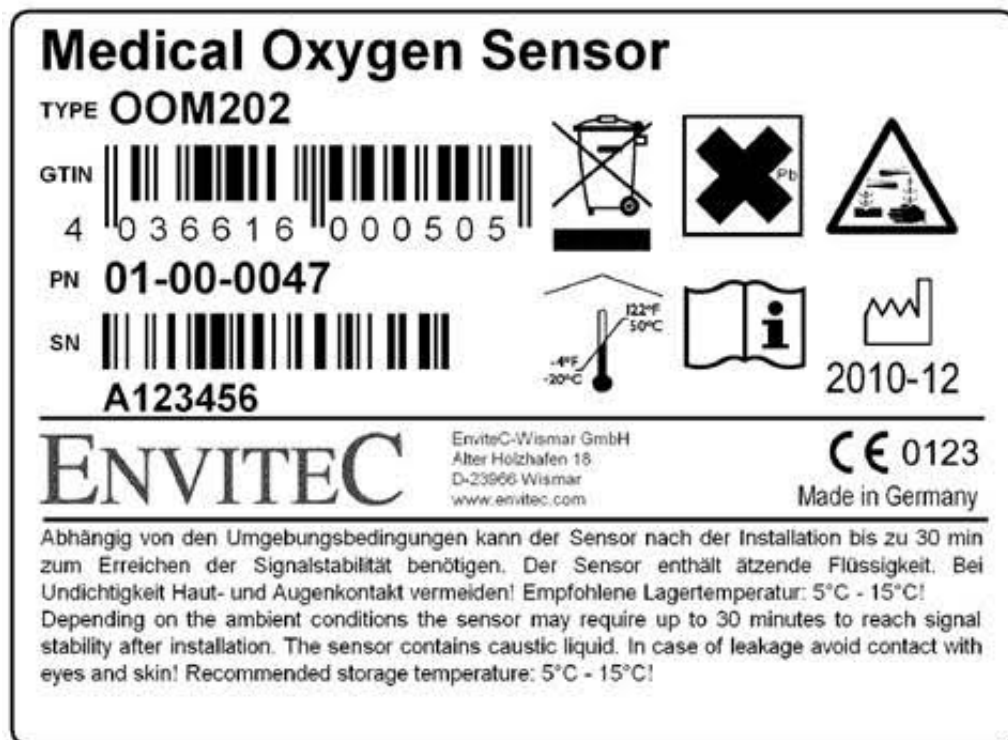
On 3 September 2015 at 14:30, Helms, Eleonore <Eleonore.Helms@honeywell.com> wrote:

Hi Steve,

Herewith the summary of what was discussed with R&D and product management:

It does not make sense to have a use-by time (considered here: time before the first use of the device AND lifetime of the sensor) since this depends predominantly on ambient conditions. The recommended ambient conditions for storage are stated on our (packaging) labels (+5° to +15°C). Therefore, we put the manufacturing date on the product label and refer to our warranty period starting with the manufacturing date.





Jessica already forwarded the current status of our standard labels to you. We never had any discussions with our Notified Body in this respect.

FYI: We are considering to amend the packaging label slightly (new symbol for “read instructions”; English text only). We are also going to introduce instructions for use (to be published on our website only), amongst others describing that the calibration of the sensor, required daily when used (active test by the respirator), ensures early detection of sensor consumption.

I suggest we change the Viamed labels accordingly.

Kind regards,

Eleonore

Von: steve.nixon.viamed@googlemail.com [mailto:steve.nixon.viamed@googlemail.com] **Im Auftrag von** Steve Nixon
Gesendet: Mittwoch, 26. August 2015 14:09
An: Helms, Eleonore
Cc: Wagner, Jessica (GE0Y); Derek Lamb
Betreff: Re: Use by dates, put into use by dates or install dates?

Dear Eleonore

It looks like there should be a **USE BY** date on the oxygen sensors or the oxygen sensor packaging. Referring to the Medical Devices guidance document MEDDEV 2.2/3 rev.3:

"The use-by time relates to the period before the first use of the device. It does not relate to the number or period of subsequent uses (the lifetime of the device)."

We as Viamed have to do exactly the same as you the OEM. So what is your interpretation and that of your notified body?

The correct symbol to use is the sand timer, with date as **YYYY-MM**

If you decide to put a **use by** date, then I believe this should default to at least the warranty period, i.e. 15 months from date of manufacture. Of course if you have the shelf life tests to prove it is OK, from a realistic or marketing point of view we could of course state a longer period.

Regards

Steve

On 14 August 2015 at 12:59, Steve Nixon <steve.nixon@viamed.co.uk> wrote:

FYI, has been added to an issue.

Steve

----- Forwarded message -----

From: **Helms, Eleonore** <Eleonore.Helms@honeywell.com>

Date: 13 August 2015 at 07:12

Subject: WG: Use by dates, put into use by dates or install dates?

To: Steve Nixon <steve.nixon@viamed.co.uk>

Cc: "Wagner, Jessica (GE0Y)" <Jessica.Wagner@honeywell.com>

Good morning Steve,

Further to your email please find attached a statement that might help in the audit. It could also be an idea in the future to publish something in this respect on your home page and to have a symbol for "Read instructions on web page before use" on the sensor.

Kind regards,

Eleonore Helms

Quality Leader Intelligent Life Care

Novar GmbH, a Honeywell Company
Dieselstraße 2
41469 Neuss, Germany
www.ackermann-clino.de

EnviteC-Wismar GmbH, a Honeywell Company
Alter Holzhafen 18
23966 Wismar, Germany
www.envitec.com

Phone: [+49 2137 17638](tel:+49213717638)
Fax: [+49 2137 17485](tel:+49213717485)
Mobile: [+49 172 2122933](tel:+491722122933)
eleonore.helms@honeywell.com

[+49 3841 360 328](tel:+493841360328)
[+49 3841 360 222](tel:+493841360222)

Registergericht: Stuttgart, HRB 401195

Aufsichtsrat: Martin Göth

Geschäftsführung: Martin Bemba, Klaus Hirzel, Marcus Lindenlaub, Marcus Ostländer

Von: steve.nixon.viamed@googlemail.com [mailto:steve.nixon.viamed@googlemail.com] **Im****Auftrag von** Steve Nixon**Gesendet:** Mittwoch, 12. August 2015 14:24**An:** Wagner, Jessica (GE0Y)**Betreff:** Use by dates, put into use by dates or install dates?

Sorry Jessica

As we are own band labelling your sensors we need the Envitec interpretation of the following:

Use by dates, put into use by dates or install dates? The auditors say that we should have something.

We have said that this is confusing because you can have a use by date of say 1st September 2015, but the sensor could then be in use for say three years.

There doesn't appear to be any appropriate ISO symbol for install by, so perhaps we should both consider adding 'Install by' dates to the sensor packaging? This then would mean that the sensors have a shelf life, so we have them deem what is a safe or appropriate shelf life. Also would we need to qualify that by adding the protect from sunshine icon...

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Steve

Steve Nixon

Director - Viamed Ltd.

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