



Derek Lamb <liquidgands@gmail.com>

AW: OBL BSI Audit 2016

1 message

Helms, Eleonore <Eleonore.Helms@honeywell.com>

8 November 2016 at 11:01

To: Derek Lamb <derek@lamb.uk.net>

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

Hi Derek,

My apologies for the late reply but we just had our annual surveillance audit, too.

I have no problems to forward the required documents to you. However, Steve did not yet sign the related contract which would constitute the basis for this information exchange. Could you please ask him to do so?

Many thanks in advance.

Kind regards,

Eleonore Helms

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Von: liquidgands@gmail.com [mailto:liquidgands@gmail.com] **Im Auftrag von** Derek Lamb
Gesendet: Montag, 24. Oktober 2016 11:39
An: Helms, Eleonore <Eleonore.Helms@Honeywell.com>
Betreff: OBL BSI Audit 2016

Dear Eleonore,

We had a BSI Audit in 2015, in which I believe you sent your technical files directly to our BSI Auditor, proof of Compliance with :

- 1/ Compliance with the Essential Requirements
- 2/ Biocompatibility (V&V)
- 3/ Risk Analysis and Control Summary
- 4/ Product Verification and Validation
- 5/ Clinical evaluation

The requirements behind OBL certificates and Virtual Manufacturers are being tightened up again.

We have had a further BSI Audit and they have raised another Major against us for the same files. as we don't have them in our system

Would it be possible for you to send me documentation from the above sections so I can add to my local Envitec OBL files.

I don't think I need complete in depth files, just evidence the sections are in compliance with CE.

The files will be confidential and only made available to BSI directly.

Regards

Derek Lamb

Viamed Ltd.