



Derek Lamb <liquidgands@gmail.com>

Fwd: RE: FW: Biocompatibility tests for Viamed Ltd.

1 message

Steve Nixon <steve.nixon@viamed.co.uk>
To: Derek Lamb <derek.lamb@viamed.co.uk>

6 August 2013 14:59

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

From: "Michael DiPietro" <Michael.DiPietro@toxikon.com>
Date: Aug 6, 2013 2:24 PM
Subject: RE: FW: Biocompatibility tests for Viamed Ltd.
To: "Steve Nixon" <steve.nixon@viamed.co.uk>
Cc: "Chaula Desai" <Chaula.Desai@toxikon.com>

Hello Steve,

Thanks for getting back to me. I have attached the quote for the tests that you are mentioning. I quoted you for two types of irritation as both have different applications and we believe both may be required. However, we are happy to perform only what you choose. The prices are for GLP testing and the turnaround times/sample requirements are all listed in our medical device testing guide (please see attached). Please let me know what you think of if you need anything else.

Best,

Michael DiPietro

Client Relations

15 Wiggins Avenue
Bedford, MA 01730
P: 781-275-3330 ext.195
F: 781-271-1136
E-mail: michael.dipietro@toxikon.com
Web: www.toxikon.com



New to Toxikon:

<http://www.toxikon.com/services/TCIR.cfm>

From: steve.nixon.viamed@googlemail.com [mailto:steve.nixon.viamed@googlemail.com] **On Behalf Of**
Steve Nixon
Sent: Monday, August 05, 2013 4:41 PM
To: Michael DiPietro
Subject: Re: FW: Biocompatibility tests for Viamed Ltd.

Thanks Michael

Steve Nixon
Viamed Ltd.
15 Station Road
Cross Hills
Keighley
West Yorkshire BD20 7DT

01535 634542

Steve

On Aug 5, 2013 8:39 PM, "Michael DiPietro" <Michael.DiPietro@toxikon.com> wrote:

Hi Steve,

I would be happy to send a quote along. Can you please provide your address/phone number for me to put you in our system and generate a quote? Thank you and have a good evening.

Best,

Michael DiPietro

Client Relations

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F: 781-271-1136
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Web: www.toxikon.com



New to Toxikon:

<http://www.toxikon.com/services/TCIR.cfm>

From: steve.nixon.viamed@googlemail.com [mailto:steve.nixon.viamed@googlemail.com] **On Behalf Of**
Steve Nixon
Sent: Friday, August 02, 2013 10:02 AM

To: info
Subject: Biocompatibility tests for Viamed Ltd.

Dear Sir/Madam

GE have passed your details on to us and they say that you may be able to assist in carrying out Biocompatibility tests on our behalf.

We have a product in development, which is an eye mask for use on babies (see photo attached). It consists of a spun-laced bandage fabric with a protective eye patch on the inner side. The mask is attached to the patient by use of Velcro fastenings, which have been ultrasonically welded to the spun-laced fabric.

In line with our CE certification we need biocompatibility testing carried out on the product. The product is usually attached to patients for 2 – 8 hrs. I believe that the first two biocompatibility classifications of <24hrs and 1 – 30 days application are identical in terms of the tests that need to be carried out, therefore we may as well cover both. Can you please confirm/advise if the following are the tests that need to be carried out?

Cytotoxicity tests to ISO 10993-5

Sensitization tests to ISO10993-10

Irritation tests to ISO10993-10

Also are Chemical Characterization tests to EN ISO 10993-18 required?

Can you please provide a quotation for the test, together with a lead-time for them to be carried out? Do you routinely test to GLP, or are there addition costs involved?

Kind regards

Steve

Steve Nixon

Director - Viamed Ltd.

3 attachments



image001.jpg

4K

13-08-06-0003viamed.pdf
125K

MED DEVICE GUIDE2013.pdf
1779K