MINISTÈRE DE L'EMPLOI
ET DE LA SOLIDARITÉ

RÉPUBLIQUE FRANÇAISE

DIRECTION DES HOPITAUX

010594

Paris, le 01 OCT. 1998

Division des équipements,
des matériels médicaux
et des innovations technologiques

Bureau des dispositifs médicaux (EM1)

Personnes chargées du dossier :
Violette GARCIA ☎ 01 40 56 43 80
Agnès PARMENTIER ☎ 01 40 56 52 83

Fax : 01 40 56 50 89

INTEGRAL PROCESS
SERVICE COURRIER
05 OCT. 1998
REÇU

INTEGRAL PROCESS
Z.A. des Boutries
12, rue des Cayennes
78703 CONFLANS STE HONORINE

A l'attention de Monsieur MONIER

Objet : Contrôle du marché des dispositifs médicaux : dispositions de l'article R.665-36 du Livre V bis du code de la santé publique.

Référence : Votre courrier du 15 septembre 1998..

Monsieur,

Après étude de votre dossier relatif aux capteurs de la mesure de la SPO2, je vous informe que ce produit est un dispositif médical actif car il existe une modification significative d'énergie au sein du dispositif médical.

Ces capteurs de la mesure de la SPO2 répondent aux dispositions de la règle 10 de l'annexe IX du Livre V bis du code de la santé publique et appartiennent à la classe IIb dans la mesure où ils sont destinés spécifiquement à surveiller des paramètres physiologiques vitaux dont les variations, notamment des paramètres des fonctions cardiaques et respiratoires, peuvent présenter un danger immédiat pour la vie du patient.

Je vous prie d'agréer, Monsieur, l'expression de mes salutations distinguées.

PAR AUTORISATION
Le Chef du Bureau EM1
Dispositifs médicaux

Guy TOUSSAINT

VIAMED

FAX REF :
Mrs K. Ventris
Medical Devices Agency
Room 11S1
Hannibal House
London SE1 6TQ
27 November 1998
0171 972 8107

Dear Mrs Ventris,

Pulse Oximeter Probes

We have recently CE marked a range of compatible Pulse Oximeter probes.

Having sought advice from our notified body BSI , yourselves the MDA, and other professional bodies we agreed that Class IIa classification was appropriate. This has since been supported by statements from German and Danish manufacturers also applying the CE mark to this product.

We have today learnt from our distributor in France that we have to supply a declaration to class IIb before he can submit a tender to supply.

We believe we have chosen the correct course and that this is a case of trade discrimination.

However if the product is eventually re-classified as IIb we will be able to comply.

Unfortunately we believe that it is not correct or acceptable to wrongly classify a product either up or down so we need clarification from external bodies.

Kind Regards,

John S. Lamb.

0171 972 8113Aeurope/MDAFAX

RS 28343 RS 28344

Viamed Limited, 15 Station Road, Cross Hills,
Keighley, West Yorkshire BD20 7DT
Tel +44 (0)1535 634542/636757 Fax +44 (0)1535 635582
Email info@viamed.co.uk
Registration No 12917565 in England

CCJL

MEDICAL DEVICES AGENCY

Safeguarding Public Health

Mr J Lamb
Viamed Ltd
15 Station Road
Crosshills
Nr. Keighley
West Yorks
BD20 7DT

Your Ref :
Our Ref : E/98/7343

Direct Line : 0171 972 8211
Direct Fax : 0171 972 8112

30 November 1998

Dear Mr Lamb,

Thank you for your enquiry which is now receiving attention.

We hope to be able to reply to your enquiry within four weeks from the date of this acknowledgement letter.

Yours sincerely,

J FARQUHARSON
European & Regulatory Affairs

VIAMED

Mrs K Ventris
Medical Devices Agency
Room 11S1
Hanibal House
London
SE1 6TQ

14 December 1998

Dear Mrs Ventris

I have been requested by Mr John Lamb to forward to you the enclosed latest statement from the Heath French Ministry regarding the Finger Probe classification.

Should you have any queries or require further information, please do not hesitate to contact us.

Yours sincerely
VIAMED

Angela Hawthorne (Mrs)

RS 28343 RS 28344

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Keighley, West Yorkshire BD20 7DT
Tel +44 (0)1535 634542/636757 Fax +44 (0)1535 635582
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CONTROLE GRAPHIQUE S.A.
4, Chemin de Villemenon - Zone industrielle - BOITE N°4 - 77257 BRIE-COMTE-ROBERT CEDEX
Téléphone : (1) 64 05 05 75 - Service commercial: Télécopieur : (1) 64 05 16 24

Date: December, 10th, 1998 **Heure:** 10:43

Dest: VIAMED **Tél.:** 00 44 1 535 634542
Stephen NIXON **Télécop :** 00 44 1 535 635582

SUBJECT :

Dear Steve,

Attached you will find a copy of the original letter sent to Integral Process by our Health French Ministry, which explains that finger probes should have to be classified Class II B.

So, they argue that you must use Annex IX, definitions 1.4 (Active Medical Device), then Chapter III (Classification) 3.2 Rule 10, which indicates that the right classification is Class II B.

Moreover, according to the above mentioned, you will have to use Annex 3 instead of Annex 5, then to get from BSI the proof of Biocompatibility for each finger probe, that means a certificate for each finger probe tested on each original unit (BAXTER, NELLCOR, etc...) like you did for cells.

I need your prompt reply.

Best regards,

Marc SABAH

(CC SC)

MEDICAL DEVICES AGENCY

Safeguarding Public Health

Mrs Angela Hawthorne
Viamed Ltd
15 Station Road
Cross Hills
Keighley
West Yorks BD20 7DT

Direct Line 0171 972 8211
Direct Fax 0171 972 8112

11 January 1999

Dear Mrs Hawthorne

Thank you for your letter dated 14 December about Finger Probe classification.

Your letter is receiving attention and we will be sending a detailed response as soon as possible.

Yours sincerely

JOHN FARQUHARSON
European & Regulatory Affairs

MEDICAL DEVICES AGENCY

Safeguarding Public Health

Mr J Lamb
Viamed Ltd
15 Station Rd
Cross Hills
Keighley
W Yorkshire BD20 7DT

Your Ref:
Our Ref: E/98/7343
Direct Line: 0171 972 8185
Direct Fax : 0171 972 8112
E-Mail : rhiggins@doh.gov.uk

23 December 1998

Dear Mr Lamb

CLASSIFICATION OF PULSE OXIMETER PROBES

Thank you for your fax of 27 November 1998 to Mrs Ventres.

In our opinion these probes are clearly active devices under Rule 10 of Annex IX of the Medical Devices Directive 93/42/EEC. If there is an argument that there could be immediate danger to the patient if the probe failed in some way due to the lack of monitoring of a vital physiological parameter then they are likely to fall into Class IIb.

We are happy to help you by giving you our views and comments but you must appreciate we are unable to give you any legal advice.

Yours sincerely

R Higgins

Rob Higgins
Regulatory Affairs Manager

CEOL

CONTROLE GRAPHIQUE S.A.
4, chemin de Villemenon - Boîte N° 4
Zone Industrielle - 77257 BRIE COMTE ROBERT CEDEX
Téléphone (1) 64 05 05 75
T[illegible] 692395 DIAGRAM
F[illegible].16-1) 64 05 38 75 (Siège Social)
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Fax (16-1) 64 05 67 18 (Sce Commercial)

Secteur
Code Client

FROM : MARC SABAH
DE :
N° FAX :

TO : UNITED
A : Mr NIXON
N° FAX :

SUBJECT : RE : MALINCROFT Copy
OBJET : URGENT

N[bre] de pages 1
DATE : Nov, 13th 98

DEAR Mr NIXON
After reading the Above mentioned Copy.
I Noticed that "Nelcor" is CERTIFIED CLASS IIb
Your ones are classified Class IIa
According to the CE MARK Regulation
it's TRUE that to be COMPATIBLE with
Nelcor's PULSE oxymetors. we Need to be
Clan IIb
Now to come back to what MALLINCKRODT
explains that means: IF COMPETITORS ARE
clan IIa, they are not COMPATIBLE, ⇒
"which is TRUE"
For your Information, we Have had the
Same Problem with Electrosurgical Handle
and Finally we were obliged to ASK "TUV"
for getting clan IIb Instead of Class IIa.
Please Call me Tuesday Morning (Nov, 16th 98) to
get a FAST Phone discussion.
Best regards
Marc