RÉPUBLIQUE FRANÇAISE

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Agence française de sécurité sanitaire des produits de santé

Saint-Denis, le 18 AOUT 2011

Direction de l'Inspection et des Etablissements
Département Inspection en contrôle du marché
Unité Inspection des Dispositifs Médicaux
Personne chargée du dossier : Charles Bartthelmé
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Mr Godfrey NGAI
Director & CEO
Modern Dental Laboratory
Units 2201-4
9 Wing Hong Street
Cheung Sha Wan, Kowloon
Hong Kong
CHINA

Réf. à rappeler LdTC3 MODERN DENTAL LABORATORY-030511-11DM405-1

Code : DIE/INS/001 – LT03 / v.04

Recommandé avec accusé de réception

Sir,

Messrs Charles BARTHELME and Régis ANDRE, inspectors of the French Health Products Safety Agency (AFSSAPS), carried out, the 3rd, 4th, 5th and 6th of May 2011, an inspection in MODERN DENTAL LABORATORY plant located Block 6, Shi Ling, Industrial Estate, Xin Wei Cun, Xi Li, Nanshan, Shenzhen, China, which you are Director & CEO.

With reference to your answers received the 2nd of August 2011, to the preliminary inspection report that has been sent to you the 13th of July 2011, you will find enclosed the final report .

The documents issued by my services are sent to you as copies. The masters are retained at AFSSAPS Inspectorate and Companies Department.

Yours sincerely

Le Directeur de l'Inspection et des Établissements

Marc STOLTZ

Enclosed : 1 final inspection report.

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Direction de l'inspection et des établissements

Département Inspection en Contrôle du Marché
Unité Inspection des dispositifs médicaux

Person in charge of the file : Charles BARTHELME
Télécopie : 00 33 (0)1 55 87 40 52
Code : DIE/INS/001-FT v.01
N./Réf. : C3 MODERN DENTAL LABORATORY China 020511-11DM404-2

FINAL INSPECTION REPORT

Subject	Inspections campaign of dental prosthesis.	
Type of Company	Manufacturing Sub-Contractor	
Company	**MODERN DENTAL LABORATORY** **Adress :Bloc 6, Shi Ling, Industrial Estate, Xin Wei Cun, Xi Li, Nanshan, Shenzhen, China.** **Fax : +(852) 2751 6049**	
Reference of the inspection document	C3 MODERN DENTAL LABORATORY China 030511-11DM404-1	
Thematic of the inspection	Dental Prothesis	
Standards	Directive 93/42/EEC for medical devices modified by the Directive 2007/47/EC of the European Parliament	
Names of the inscpectors	Mr BARTHELME Charles charles.barthelme @afssaps.sante.fr phone : 00. 33. 1.55.87.40.57	Mr ANDRE Regis (on training) Regis.andre@afssaps.sante.fr phone : 00.33.1.55.87.40.62
Dates of the inspection	from the 3rd of May to the 6th of May 2011	
Scheduled Inspection	☒ Yes ☐ No	UNEXPECTED ☐ Oui ☒ Non
Inspection on an enquiry or on a request	☐ Yes ☒ No Préciser le donneur d'ordre (Afssaps, OMS, OCDE, EMA, DEQM...)	

I. ANSWERS TO NON COMPLIANCES

	ESTABLISHED FACTS DURING THE INSPECTION	FINAL ANSWER
1	**Staff** Delegations for critical functions as releasing, vigilance, recalls, complaints, irregularity processing, treatment of defective products... should be described and written in the description of the duties of the member of staff in charge of these duties.	**Acceptable answer**
2	**Quality and traceability of the documentation** Documentation concerning quality and traceability, on paper support or on electronic data support, has to be protected from damages that may be caused by fire and water and the reading means of electronic data recorded have to be conserved. A program intended to survey the expiry dates of the raw material EC certificates shall be implemented.	**Acceptable answer**
3	**External Audits programs** There is no program for subcontractor's audits (suppliers of raw materials and service analysis).	**Acceptable answer**
4	**Metrology - Calibration of equipments** Critical measurement Equipment that are subject to annual calibrations must be labelled as such with an expiry date, to prevent their use beyond an expiry date.	**Acceptable answer**
5	**Release** The release of dentures at the end of the production is validated before the packaging operations.	**Remark maintained because the response provided does not address the subject of the non-compliance. The release of the dentures, at the end of production, shall be done after the packaging operations.**
6	**Traceability** Traceability of the thirteen final inspection operations before releasing is not effective.	**Acceptable answer**
7	**Cross-contamination prevention** It has been observed a reprocessing area which was opened, without protection, on a production area in activity.	**Acceptable answer. More simply, the doors of the local in renovation have to stay closed as long as the renovation is not finished.**
8	**Status** The implementation of a quarantine area for raw materials is necessary to distinguish the quarantine status from the released status.	**Acceptable answer**

9	**Fist in first out and expiry date of the raw materials** Fist in first out and expiry date of the raw materials are theoretically followed but not traced by computer or follow-up system.	**Acceptable answer**
10	**Trend analysis of temperature** The trend analysis of temperature for the storage area of the liquid is not carried out. There is no procedure to describe what happens with the product in case of interruption of air treatment.	**Acceptable answer**
11	**Areas** It has been observed an opened window near prosthesis in disinfection. It is recommended to separate clearly the area assigned to the purpose of disinfection from the area assigned to the handling of impressions.	**Remark maintained, waiting the result of the feasibility study for the installation of an automatic machine which would give a closed environment for disinfection**
12	**Labelling** Bottles with liquid detergent (Sporax) or bleach used for disinfecting or cleaning are not labelled.	**Acceptable answer, but when diluted preparations of disinfectant are realized in large containers by MODERN DENTAL LABORATORY, these containers have to be correctly labelled**
13	**Contract between MDL (Shenzhen, China) and LABOCAST (Paris, France)** Data like : - Essential Requirements of the European Directive 93/42/CEE applicable to medical devices ; - Exclusive use of CE marked raw materials must be listed in the contract established between MDL (China) and LABOCAST (France).	**Acceptable answer. The new contract between MDL and Labocast shall be quickly established and signed.**

II. FINAL CONCLUSION

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Risks established

This inspection has not showed a risk for public health at the time of the inspection for the manufacturing of dental prosthesis by MODERN DENTAL LABORATORY for the French market.

The inspection carried out in MODERN DENTAL LABORATORY plant in Shenzhen (China) from the 3rd to the 6th of May 2011 has been realized in the framework of the campaign of inspections of the dental prosthesis manufacturers.

It appears, after the inspection, that acceptable answers have been given to the set of deviations and remarks notified in the preliminary report except from points 5 and 11 for which corrective actions shall be quickly implemented.

8th August 2011.

Signature of the inspector :

Charles BARTHELMÉ

AFSSAPS Inspector