

Saint-Denis, le 04 MAR. 2016

Direction de l'inspection

Pôle inspection des essais et des vigilances

Personne chargée du dossier :

Téléphone :

Télécopie :

e-mail :

Réf. : MV-Nagor-08122015-LC3-MHRA-15IPV021

Code : DI_INS001_LT06_V07

NOTES ! 2016030700133

**Head of Biosciences and Implants Unit
Medicines and Healthcare products
Regulatory Agency (MHRA)
151 Buckingham Palace Road, London,
SW1W 9SZ
United Kingdom**

Lettre recommandée avec accusé de réception.

Purpose : Materiovigilance inspection of NAGOR-BIOSIL Ltd Company.

Company	Address	Period	ANSM Staff
NAGOR-BIOSIL Ltd.	127/129 Deerdykes View Westfield Industrial Estate Cumbernauld, Scotland Glasgow G68 9HN UNITED KINGDOM.	From Tuesday 8 th to Wednesday 9 th December 2015.	ANSM Inspector.

Dear Sir,

On behalf of the Director General of ANSM, I entrusted _____, ANSM inspector, the inspection mission of NAGOR-BIOSIL Ltd plant located 127/129 Deerdykes View, Westfield Industrial Estate, Cumbernauld, Scotland, Glasgow G68 9HN, United Kingdom.

This inspection was carried out from Tuesday 8th to Wednesday 9th December 2015 and concerned the compliance of the materiovigilance activities performed by this company, pursuant to article 10 and Annex II section 3.1 of the Directive 93/42/EEC applicable to medical devices, as far as NAGOR-BIOSIL Ltd. Company holds the EC certification of breast implants it places on the European market, particularly on the French market.

As a result of this mission, you will find enclosed the preliminary and final inspection reports with the letter sent to the attention of NAGOR-BIOSIL Ltd Director of Regulatory Affairs and Quality Assurance.

Yours sincerely.

Chef de Pôle
Inspection des Essais
et
des Vigilances

Attached :

- Preliminary and final inspection reports ;
- Letter sent to the attention of NAGOR-BIOSIL Ltd Director of Regulatory Affairs and Quality Assurance.