

1.8.1 PHARMACOVIGILANCE SYSTEM

According to Article 8 (ia) of the Directive 2001/83/EC a pharmacovigilance system master file is available under the number [REDACTED].

1.8.1.1. PROOF OF ESTABLISHING A QUALIFIED PERSON IN PHARMACOVIGILANCE

Laboratoires Gilbert, holder of the following product:

CHLORHEXIDINE ALCOOLIQUE GILBERT HEALTHCARE 2%, solution pour application cutanée

have a qualified person responsible in pharmacovigilance :

[REDACTED]
Pharmacien Responsable

Directeur Général Délégué

The registration proof in Eudravigilance base of [REDACTED] is presented in Appendix 1.8.1.

1.8.1.2. MEMBER STATE WHERE THE QUALIFIED PERSON OPERATES

The qualified person responsible in pharmacovigilance lives and operates in France.

1.8.1.3. CONTACT INFORMATION OF THE QUALIFIED PERSON

The contact information of the qualified person responsible in pharmacovigilance are:

[REDACTED]
928 avenue du Général de Gaulle

14200 Hérouville Saint-Clair

[REDACTED].

[REDACTED].

1.8.1.4. HOLDER ATTESTATION THAT CERTIFY THE NECESSARY RESOURCES TO UNDERTAKE THE RESPONSIBILITIES DESCRIBED IN TITLE IX

The holder attestation is presented in Appendix 1.8.2.

1.8.1.5. LOCALITY ADDRESS OF THE PHARMACOVIGILANCE SITE MASTER FILE

The Pharmacovigilance Site Master File is kept in the head office of Laboratoires Gilbert:

928 Avenue du Général de Gaulle,
14200 Hérouville Saint-Clair.

Appendix 1.8.1

REGISTRATION PROOF IN EUDRAVIGILANCE BASE OF [REDACTED]



User Declaration

Part A

- The undersigned QPPV/RP/trusted Deputy User or Individual User declares that he/she will:
- keep the password provided by the European Medicines Agency for the access to EudraVigilance a secret, remember the password and destroy the e-mail/slip on which it is printed;
 - not write the password down in any way that it could be understood by anyone else;
 - never tell anyone the password or allow anyone else to use it. If it happens, the user is responsible for any security breaches that may occur to the data stored with EudraVigilance;
 - Inform the Agency immediately if the user suspects that anyone knows the password. The Agency administrators can be contacted during normal office hours. In such case, the user must request a new password immediately from the Agency;
 - inform the Agency immediately in writing of any changes in his contact details as specified in the user registration form;
 - **inform the Agency immediately in writing about any changes of his/her access rights** (e.g. end of employment with the registered organisation, change of department within the registered organisation etc) .

Part B

- The undersigned QPPV/RP or trusted Deputy User declares that he/she will:
- **inform the Agency immediately in writing about any changes affecting the access rights** (e.g. end of employment with the registered organisation, change of department within the registered organisation etc.) of any registered EudraVigilance user in relation to the organisation as indicated below.

Please note that the access to EudraVigilance will be denied if the user enters the incorrect password in the login process three times in a row on the same day.

The Agency can refuse the registration of a user for any valid reason.

The undersigned act in the following role:

- QPPV/RP
 Trusted Deputy User
 Individual User

Organisation name (NCA/ MAH/ Sponsor): LG HOME0

Organisation type:

- National Competent Authority
 Regional Pharmacovigilance Centre
 Marketing Authorisation Holder
 Applicant
 Commercial Sponsor
 Non Commercial Sponsor

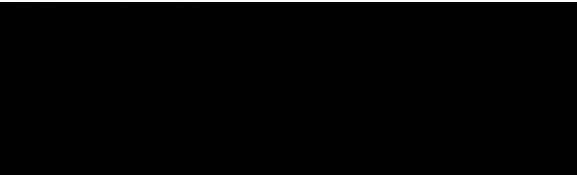
User details:

Street: Avenue du Général de Gaulle

City: Hérouville Saint-Clair

Postcode: 14200

Country: FRANCE



Date: 28/04/2016

Signature: 

Submitted personal data is processed in accordance with Regulation (EC) 45/2001 on the protection of individuals with regard to the processing of personal data by the Community institutions and bodies and on the free movement of such data. These personal data are required to manage the EudraVigilance database, in accordance with art. 57(1) (j) of Regulation (EC) 726/2004, in order to verify the identity of the users of the system and related pharmacovigilance activities. Your address, including e-mail address, will be used to send you technical instructions and other pertinent communications. They are processed by the European Medicines Agency and other National Competent Authorities exclusively for the purpose for which they are collected. You are entitled to access, rectify and block these data in accordance with the provisions of Regulation (EC) 45/2001. You may exercise these rights by contacting the European Medicines Agency. You have also the right of recourse to the European Data Protection Supervisor (www.edps.europa.eu) at any time.

Appendix 1.8.2

**HOLDER ATTESTATION THAT CERTIFY THE NECESSARY RESOURCES TO UNDERTAKE THE
RESPONSIBILITIES DESCRIBED IN TITLE IX**



DÉCLARATION DE MOYENS EN MATIÈRE DE PHARMACOVIGILANCE

Nous, le signataire :


LABORATOIRES GILBERT
928 Avenue du Général de Gaulle
14200 Hérouville Saint-Clair
France

Exploitant de l'Autorisation de mise sur le marché suivante :

CHLORHEXIDINE ALCOOLIQUE GILBERT HEALTHCARE 2%, solution pour application cutanée

Nous attestons que nous disposons des moyens nécessaires pour s'acquitter des tâches et des responsabilités énoncées au titre IX de la Directive 2001/83/CE.

Hérouville Saint-Clair, le 28 Novembre 2018


Pharmacien Responsable
Directeur Général Délégué

[REDACTED]

[REDACTED]
[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] [REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]

[REDACTED] [REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]

[REDACTED] [REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]

[REDACTED] [REDACTED]
[REDACTED]
[REDACTED]

[REDACTED] [REDACTED]
[REDACTED]
[REDACTED]

[REDACTED] [REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]

[REDACTED]

[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]

[REDACTED]

[REDACTED] [REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]