

Certificate of suitability No. R1-CEP 2004-180-Rev 00

1 *Name of the substance:*

2 **NITROGEN**

3 *Name of holder:*

4 **AIR LIQUIDE**

5 75, Quai d'Orsay

6 France-75007 Paris

7 *Site(s) of production:*

8 **AIR LIQUIDE**

9 507, Avenue Henri Poincaré

10 France-77550 Moissy Cramayel

11 **AIR LIQUIDE**

12 2 Rue Sauzay

13 Lieu Dit Le Sauzay

14 France-69320 Feyzin

15 **AIR LIQUIDE**

16 86, Rue de la Vieille Espérance

17 Belgium-4100 Seraing

18 **AIR LIQUIDE**

19 Haven 725, Scheldelaan 600

20 Belgium-2040 Antwerpen

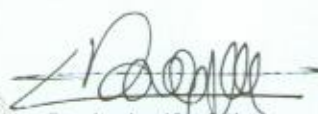
21 **THIS CERTIFICATE SUPERSEDES THE PREVIOUS CERTIFICATE**

22 **R0-CEP 2004-180-REV 00**

23 After examination of the information provided on the manufacturing method and
24 subsequent processes (including purification) for this substance on the site(s) of
25 production mentioned above, we certify that the quality of the substance is suitably
26 controlled by the current version of the monograph **NITROGEN** no. 1247 of the
27 European Pharmacopoeia, current edition including supplements.

28 The holder of the certificate has declared the absence of use of material of human or
29 animal origin in the manufacture of the substance.

- 30 The submitted dossier must be updated after any significant change that may alter the
 31 quality, safety or efficacy of the substance.
- 32 Manufacture of the substance shall take place in accordance with the Good
 33 Manufacturing Practice and in accordance with the dossier submitted.
- 34 Failure to comply with these provisions will render this certificate void.
- 35 This certificate is renewed from **13 July 2010** according to the provisions of Resolution
 36 AP-CSP (93) 5 as amended, and of Directive 2001/83/EC and Directive 2001/82/EC
 37 and any subsequent amendment, and the related guidelines.
- 38 This certificate has:
 39 lines.


 On behalf of the
 Director of EDQM



Strasbourg, 25 June 2010

DECLARATION OF ACCESS *(to be filled in by the certificate holder under their own responsibility)*

Air Liquide, as holder of the certificate of suitability

R1-CEP 2004-180-Rev 00 for NITROGEN

hereby authorises
(name of the pharmaceutical company)

to use the above-mentioned certificate of suitability in support of their application(s) for the following
 Marketing Authorisation(s): *(name of product(s) and marketing number(s), if known)*

The holder also certifies that no significant changes to the operations as described in the CEP dossier
 have been made since the granting of this version of the certificate.

Date and Signature *(of the CEP holder)*: