

CE Technical Documentation Review Report

Applicant:

Longkou Double Eagle Medical Device Co., Ltd.

The north to the good-seeds farm, Longkou,

Shandong, P.R. China 16800873.001

Report Number:

Examination intent:

Examination the completeness of the Technical

Documentation according to the requirements of the Medical Devices Directive 93/42/EEC Annex VII

Product(s):

1. Protective devices against diagnostic Medical X-

radiation

---Lead Rubber, Lead Apron, Lead Gloves,

Lead Spectacles, Lead Screen

2. Air Bed for Medical Use

Type(s)/Model(s):

Classification:

Class I

(according to manufacturer's declaration)

Examination period:

Oct.25.2011

Date of expiry:

Oct.24.2016

Review result:

During the examination of the provided Technical Documentation (No.LKSY-FHYP-001, Revision: B/0, dated 2011-09-21; No.LKSY-CQC-001, Revision: dated 2011-09-21), no Non-compliance according to the requirements of the Medical Devices Directive 93/42/EEC Annex VII was detected.

TÜV Rheinland (China) Ltd. Beijing Operation

Yuhong GAEN

Manager (Beijing Operation)

Medical Services

Rev.01, 2002-10-10

