

## Title: Transition Plan 13485 Notice

*Changes from previous edition of this document are indicated in red text.*

### 0. OBJECTIVE

The purpose of this document is to inform all licensees about the procedures defined by the **Certi W**® to manage the transition of their certificates ISO 13485 considering the new edition of the standard (March 2016). This procedure represent the result of what defined by IAF through its own information document IAF ID 09 edition 1 and by Latak, our Accreditation Body and EA MLA international agreements signatory.

### 1. INTRODUCTION

The new edition of the standard ISO 13485 entails the need by all the licensees **Certi W**® to adjust their management systems by recognizing all the changes – and there are many - introduced by the International Organization for Standardization (ISO).

Starting in March 2016 **Certi W**® has planned a schedule of training courses with the aim of informing and training whoever is interested about the innovations introduced by analyzing in detail the new regulatory requirements and the possible effects on their implemented and certified management systems.

**Certi W**® also informs you that it will be possible continue to use the previous version of the standard for a transitional period of THREE years from the issue date of the new edition of the standard (in March 2016) at the end of which each certification will cease of validity and the previous edition of the standard will no longer be taken as reference for its own management systems.

The entire operational staff **Certi W**® is already trained and qualified, according to our own qualification procedures, to conduct assessments of compliance according to the new edition of the standard.

### 2. MANAGEMENT OF THE TRANSITION: DEADLINES AND PROCEDURES

**Certi W**® has defined its own operating procedures for management of the transition to the certificates issued compared to the standard ISO 13485 ed. 2003 considering the requirements set by their own Accreditation Body - Latak - with the least possible burden in terms of activities for its customers.

First of all **Certi W**® suggests to all its licensees to prepare immediately a plan for the management of the transition of its management system also considering the

fact that the changes introduced by the new edition of the standard aren't at all negligible and must be taken into consideration and managed properly.

### **Verification of Gap Analysis (optional)**

Starting in the month of March 2016 and for the entire period of transition (THREE years) will be possible to request, turning to the offices of **Certi W ®**, an exceptional finalized audit to evaluate the deviation of your certified management system in regard to the requirements of the new edition of the standard ISO 9001. The cost of that exceptional audit for day/man activity, is defined by the contract already existing between all licensees and the **Certi W ®**. At the end of that activity will be issued a Report of Assessment including the analysis of the deviation (Gap Analysis) usable for the preparation of the own Plan of Action needed for the management of transition.

### **Time period May 2016 - December 2016**

**Certi W ®** will fulfil all the activities provided for the verification (certification, surveillance and re-certification) according to the previous version of the standard ISO 13485: 2003 formalizing and notifying to all its own licensees through the Report of Assessment the request for provision of specific Action Plan for the management of the transition – classifying as "observation" that request as provided by its own procedures.

**Certi W ®** will no longer provide additional time of verification as regards to the provisions of the existing contracts, therefore will not bear with any additional costs its own licensees in implementing the necessary planned transition.

Be advised that the expiry of the issued certificate following the verification may not exceed the day preceding the expiry of the fixed transition period (thirty-six months / three years of the date of issuance of the official standard).

### **Time period January 2017 - end of the transition period**

**Certi W ®** will no longer perform activities of first certification referring to the previous edition of the standard ISO 13485: 2003.

**Certi W ®** will instead continue to fulfil all the activities provided for the verification (surveillance and re-certification) according to the previous version of the standards ISO 13485:2003 formalizing and notifying to all its own licensees through the Report of Assessment the request for provision and implementation of specific Action Plan for the management of the transition – classifying that request as "minor nonconformance" according to its own procedures.

**Certi W ®** will no longer provide additional time of verification as regards to the provisions of the existing contracts, therefore will not bear with any additional costs its own licensees in implementing the necessary planned transition.

Be advised that still, in this last case, the expiry of the issued certificate following the verification may not exceed the day preceding the expiry of the fixed

transition period (thirty-six months / three years of the date of issuance of the official standard).

**From March 2019 (thirty-six months since the new standard edition)**

**Certi W ®** will no longer fulfil any activity using as a reference the previous edition of the standard ISO 13485:2003.

Each Certificate of Registration issued as of three years (thirty-six months) of the official issue date of the standard will automatically expire and will not be possible any kind of re-certification losing each historical validity of the owned certifications.

**3. INFORMATION AND UPDATES**

All offices of the **Certi W ®** are at your disposal for any clarification and / or information on the operating procedures described in the present document.

Any further changes that has been introduced or required clarification will be communicated through the dispatch of the present document updated conveniently.