**REPUBLIC OF TURKEY**

**MINISTRY OF HEALTH**

**TURKISH DRUG AND MEDICAL DEVICES AGENCY**

**Announcement No. 2020/KK-1 amending Announcement No. 2019/KK-6 on Granting a Period of Stay in the System for products whose certificates have expired or are about to expire**

As you know, medical devices put in the market in accordance with the Medical Device Regulations are registered by means of the Product Tracking System (UTS) as from 12/06/2017 under the approval no. E.1967 issued by this agency on 02/06/2017 to introduce the Medical Device Registration Screens.

In order to ensure importers and manufacturers not to suffer any problems in uploading their documents to the UTS, to ensure them to use the UTS in an efficient way and to ensure harmonious use of the UTS, EC certificates uploaded to the UTS for registration purposes, declarations of conformity valid for a limited time, and the products covered by them are allowed to remain in the UTS for a period defined in accordance with the procedure and criteria stipulated in the *Announcement amending Announcement No. 2019/KK-6 on Granting a Period of Stay in the System for products whose EC certificates have expired or are about to expire,* dated 27/03/2019.

However, both the internal audits performed by the Medical Device Registration and Control Department of the undersigned Turkish Drug and Medical Devices Agency and the feedback and demands received from medical industry companies indicate that after the Singular Tracking Process was activated in the UTS, certain parts and/or descriptions and/or annexes of the above mentioned Announcement need to be amended, updated or deleted or to be replaced with more descriptive ones, and that such amendment, update, deletion or replacement must be made in the flow chart enclosed to the Announcement in question.

Therefore:

1-If an EC certificate or Declaration of Conformity has been registered as ‘valid for a limited period’ in the UTS, the holder or issuer thereof should issue a letter of undertaking in accordance with the format given in Annex A enclosed hereto and should send a copy of the relevant renewed and valid certificate or declaration to the undersigned Agency before the limited period of validity in question expires, in which case the products covered by that certificate or declaration will be allowed to stay within the UTS for 60 days as from the expiry date set in the UTS for that certificate or declaration or as from the expiry date of the revision period set in the UTS for that certificate or declaration once for all,so that the holder or issuer will be granted time for receiving Apostille approval for its renewed certificate or declaration and for uploading the same to the UTS.

2-Upon performing the conditions specified in Paragraph 1 above, the holder’s or issuer’s registration will be revised in the UTS, so that the products covered by its Declaration of Conformity registered as ‘valid for a limited period’ in the UTS will be allowed once for all to stay in the UTS for 60 days as from the expiry of date of the revision set for the Declaration in the UTS.

3-After such EC Certificate or Declaration of Conformity registered as ‘valid for a limited period’ in the UTS has expired, the holder or issuer thereof should issue a letter of undertaking in accordance with the format given in Annex B enclosed hereto and should send a copy of the relevant renewed and valid certificate or declaration to the undersigned Agency within maximum five business days as from the expiry date, in which case the products covered by that certificate or declaration will be allowed to stay within the UTS for 60 days as from the expiry date set in the UTS for that certificate or declaration, so that the holder or issuer will be granted time for receiving Apostille approval for its renewed certificate or declaration and for uploading the same to the UTS.

4-None of the products for which Singular Tracking Process has been started in the UTS will be granted any period to stay within the UTS.

5-This Announcement supersedes and replaces *Announcement amending Announcement No. 2019/KK-6 on Granting a Period of Stay in the System for products whose EC certificates have expired or are about to expire,* dated 27/03/2019.

NOTE: In order to avoid delaying of the processing of applications, correct document type must be selected in the Electronic Application System (EBS). For this purpose, select ‘Application for Extension of Time with Hardcopy Letter of Undertaking’ or ‘Application for Extension of Time with Softcopy Letter of Undertaking’ depending on the fact that whether your letter of undertaking is hardcopy or softcopy.

**Annexes**

1-Draft Letter of Undertaking (Annex A and B ) ( 2 pages)

# 2- Flow chart for extension of time in the UTS(Annex C ) ( 1 page)

**Annex A**

**Our reference:**

**Subject:** Letter of Undertaking for EC Certificate/Declaration of Conformity

**To: REPUBLIC OF TURKEY**

**MINISTRY OF HEALTH**

**TURKISH DRUG AND MEDICAL DEVICES AGENCY**

**ANKARA**

This is to certify that the EC Certificate and/or Declaration of Conformity covering the products we manufacture or import and listed below in accordance with the Medical Device Regulations were renewed. Please find a copy of the renewed and valid certificate or declaration, for which we will obtain Apostille approval, enclosed hereto. We hereby declare that if you allow our above mentioned document(s) to remain in the UTS to grant us time to upload our renewed document(s) in the UTS and to receive Apostille approval for them, our products listed below have been manufactured within the validity period of our document(s) in question, and we hereby undertake to deliver our products whose document(s) will expire on ../../…. to consumers until ../../….

Address: Date:

 Signature/Seal

Enclosed:

1-Copy of the renewed document(s)

2-List of Products

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| **Document Number** | **Primary Product Number** | **Quantity** |
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**Annex B**

**Our reference:**

Subject: Letter of Undertaking for expired EC Certificate/Declaration of Conformity

**To: REPUBLIC OF TURKEY**

**MINISTRY OF HEALTH**

**TURKISH DRUG AND MEDICAL DEVICES AGENCY**

**ANKARA**

This is to certify that the EC Certificate and/or Declaration of Conformity covering the products we manufacture or import and listed below in accordance with the Medical Device Regulations were renewed. Please note that the validity period(s) of the document(s) in question expired within 5 business days as from the date hereof. Please find a copy of the renewed and valid certificate or declaration, for which we will obtain Apostille approval, enclosed hereto. We hereby declare that if you allow our above mentioned document(s) to remain in the UTS to grant us time to upload our renewed document(s) in the UTS and to receive Apostille approval for them, our products listed below have been manufactured within the validity period of our document(s) in question, and we hereby undertake to deliver our products whose document(s) will expire on ../../…. to consumers until ../../….

Address: Date:

 Signature/Seal

Enclosed:

1-Copy of the renewed document(s)

2-List of Products

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| **Document Number** | **Primary Product Number** | **Quantity** |
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