

TO ALL to whom these present shall come I **Justin Sean Kelly** of Butcher and Barlow LLP  
a notary public duly authorised, sworn, admitted and practising within the United Kingdom  
of Great Britain and Northern Ireland do hereby CERTIFY that the annexed document is a  
:-

1. Letter of Declaration for No Changes to Products in respect of Shandon Diagnostics  
Limited and signed by Heather Gallacher, Senior Regulatory affairs Manager

In testimony whereof I have hereunto subscribed my name and affixed my seal of office this  
20<sup>th</sup> day of August 2020 at Moss Lane, Bramhall, Cheshire SK7 1BA



**Justin Sean Kelly**  
**Notary Public**  
**England and Wales**

**Justin S Kelly**  
Notary Public  
Butcher & Barlow Solicitors & Notaries  
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## Letter of Declaration

For Products have No Changes

To Whom It May Concern,

On behalf of **Shandon Diagnostics Limited, a subsidiary of Epredia**, this letter is to state that there are NO CHANGES to Products themselves listed in Table 1, as our manufacturing site and Quality Management System remain the same:

Table 1 Product List

No.	Product Name	Model	License Number
1	Thermo Scientific Excelsior AS	Excelsior AS	CFDA(I)20161408
2	Thermo Scientific Revos	Revos	CFDA(I)20190239
3	Thermo Scientific Gemini AS	Heated/Unheated	CFDA(I)20160809

Signature: 

Date: 07 AUG 2020

Heather Gallacher

Senior Regulatory Affairs Manager

On behalf of Shandon Diagnostics Limited, a subsidiary of Epredia



致所有相关人：

本人，Justin Sean Kelly，隶属于 Butcher and Barlow LLP 公证处 - 本公证处在英国境内经过正式授权，宣誓，承认并执业 - 本人证明以下随附文件：

- 产品无变化声明信 - 由珊顿诊断有限公司出具，并由其公司的高级法规注册经理 Heather Gallacher 签署

作为证词，我在此签署了我的名字并加盖了公司印章。

2020 年 8 月 20 日

Moss Lane, Bramhall, Cheshire, SK7 1BA

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Justin Sean Kelly

公证处

英格兰和威尔士

印章：

Justin S Kelly

公证处

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## 声明信

### 产品无变化声明

致相关人，

我谨代表备案人 **Shandon Diagnostics Limited, a subsidiary of Epredia** 在此声明，由于制造地址和质量体系保持不变，表 1 中列出的产品本身在此次变更申请前后没有任何变化。

表 1 产品列表

编号	产品名称	型号规格	备案号
1	自动组织脱水机 Thermo Scientific Excelsior AS	Excelsior AS	国械备 20161408 号
2	组织脱水机 Thermo Scientific Revos	Revos	国械备 20190239 号
3	染色机 Thermo Scientific Gemini AS	Heated/Unheated	国械备 20160809 号

签名:

日期:

Heather Gallacher

高级法规注册经理

代表 Shandon Diagnostics Limited, a subsidiary of Epredia