The European Association
Medical Devices - Notified Bodies

TEAM-NB A.I.S.B.L.
Business Center Sauheid
Au Joba 9
B – 4053 Embourg BELGIQUE
Tel.: + 32 (0)4 254 55 88

E-mail: secretary@team-nb.org
Web: http://www.team-nb.org
Bank : IBAN BE09 3401 5174 8757
VAT : BE 0864.640.677

Editor : Francoise SCHLEMMER	Date : 09/05/2018

Position paper
Elements for addendum contract in the framework of the transition period

This document is proposing template on added clauses for agreement between Manufacturers and Notified Bodies regarding the transition period.

As a statement this paper is referring to Notified bodies as the organizations which issued the MDD and/or AIMDD certificates even if designation is considered as void per article 120,1.

As a reminder, **Art 120, 3:**
By way of derogation from Article 5 of this Regulation, a device with a certificate that was issued in accordance with Directive 90/385/EEC or Directive 93/42/EEC and which is valid by virtue of paragraph 2 of this Article may only be placed on the market or put into service provided that from the date of application of this Regulation it continues to comply with either of those Directives, and provided there are no significant changes in the design and intended purpose. However, the requirements of this Regulation relating to post-market surveillance, market surveillance, vigilance, registration of economic operators and of devices shall apply in place of the corresponding requirements in those Directives.

Without prejudice to Chapter IV and paragraph 1 of this Article, the notified body that issued the certificate referred to in the first subparagraph shall continue to be responsible for the appropriate surveillance in respect of all of the applicable requirements relating to the devices it has certified.

Topics to be in contract:

1. This amendment to the current contract between NB and customer is valid in the period up to May 26th, 2024 or the end of validity of the MDD and/or AIMDD certificate(s) issued, whatever is the shortest.

2. The manufacturer is obliged to comply with:
    a. MDD and/or AIMDD and the added documents (2007/47 and 920, …)
    b. National requirements/legislation that may still be in place and relevant to MDD and/or AIMDD
    c. MDR requirements relating to post-market surveillance, market surveillance, vigilance, registration of economic operators of devices shall apply at the date of May 26th, 2020 in place of the corresponding requirements in those Directives.
    d. Requirements to provide the notified body with all relevant information and access for the notified body to conduct its activities including unannounced audits
3. The validity of the certificates can only be maintained provided there are no significant changes in the design and intended purpose of the product within the certificate. This applies to devices certified before May 26, 2020.
4. The interpretation of significant change is as per agreed with the NB.
5. The notified body will perform the surveillance audits and assessment of the customer in order to verify the continuing compliance of MDD and/or AIMDD requirements and MDR requirements for the post-market surveillance, market surveillance, vigilance, registration of economic operators are fulfilled.
6. CE certificates cannot be extended, renewed, reinstated or reissued after May 26 2020. CE certificates updates can be allowed such as corrections, scope reductions, EU representative changes, name changes, new sites,…
7. If any part of this contract is violated, NB XXXX reserves the right to cancel certificates, with immediate effect.