The European Association Medical devices - Notified Bodies

TEAM-NB A.I.S.B.L.
Boulevard Frère Orban 35A
B – 4000 Liège BELGIQUE
Phone: + 32 (0)4 254 55 88
Fax: + 32 (0)4 254 55 89

E-mail: secretary@team-nb.org
Web: http://www.team-nb.org
Bank ING: 340-1517487-57
IBAN BE09 3401 5174 8757

Editor : Francoise SCHLEMMER	Date : November 7th

Draft TEAM-NB Position Paper

How and whether to Audit Authorized Representatives?

Following a discussion, we intend to agree to establish a list of the minimum to assess in auditing a Manufacturer outside Europe regarding his Authorised Representative (AR) agreement.

The items to check are:

- ✓ Manufacturer should have identify an AR;
- ✓ there should be a single AR for each product;
- ✓ a final agreement should exist;
- ✓ the agreement should follow the MEDDEV;
- ✓ there should be a signed agreement before the EC declaration of conformity is signed;
- ✓ if the Manufacturer outsourced vigilance or other processes to the AR, there should need Standard Operating Procedures and possibly an audit;
- ✓ NB should be notified in case of change of AR.

There will be an interest to discuss whether an AR could be considered as a crucial supplier.