IVDD – Directive 98/79/EC – Declaration of Conformity	
Manufacturer:	OBI ApS, c/o Bruno Graversen, Jakob Møllers Gade 4, DK-9560 Hadsund, Denmark
Product:	**v-TAC Connect Software**
Classification:	Not listed in List A or List B in IVDD Annex II, not for performance evaluation and not for self-testing
Conformity Assessment Route:	Annex III of IVDD 93/42/EEC as transposed into law in the member states where the device is placed on the market.
We herewith declare that the above mentioned products meet the provisions of the Council Directive 98/79/EEC for In-vitro Diagnostic Medical Devices. **All supporting documentation is retained under the premises of the manufacturer.**	
Standards applied:	EN 980:2008 Symbols for use in the labelling of medical devices. EN ISO 13485:2012/AC:2012 Medical devices - Quality management systems - Requirements for regulatory purposes (partly) EN 13612:2002/AC:2002 Performance evaluation of in vitro diagnostic medical devices. EN ISO 14971:2012 Medical devices - Application of risk management to medical devices. EN ISO 18113-1:2011 In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 1: Terms, definitions and general requirements. EN ISO 18113-3:2011 In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 3: In vitro diagnostic instruments for professional use. EN 62304:2006/AC:2008 Medical device software - Software life-cycle processes. EN 62366:2008 Medical devices - Application of usability engineering to medical devices.
Notified Body:	Not required for IVDD Annex III conformity
Start of CE-marking:	Release for distribution
Place, Date of Issue:	Hadsund, 2015-11-03
Signature:	Bruno Graversen, CTO

Doc. No. OBI Medical-2059 #1.0