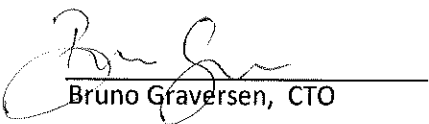


IVDD – Directive 98/79/EC – Declaration of Conformity	
Manufacturer:	OBI ApS, c/o Bruno Graversen, Jakob Møllers Gade 4, DK-9560 Hadsund, Denmark
Product:	v-TAC Connect Software
Classification:	Not listed in List A or List B in IVDD Annex II, not for performance evaluation and not for self-testing
Conformity 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.
<p>We herewith declare that the above mentioned products meet the provisions of the Council Directive 98/79/EEC for In-vitro Diagnostic Medical Devices.</p> <p>All supporting documentation is retained under the premises of the manufacturer.</p>	
Standards applied:	<p>EN 980:2008 Symbols for use in the labelling of medical devices.</p> <p>EN ISO 13485:2012/AC:2012 Medical devices - Quality management systems - Requirements for regulatory purposes (partly)</p> <p>EN 13612:2002/AC:2002 Performance evaluation of in vitro diagnostic medical devices.</p> <p>EN ISO 14971:2012 Medical devices - Application of risk management to medical devices.</p> <p>EN ISO 18113-1:2011 In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 1: Terms, definitions and general requirements.</p> <p>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.</p> <p>EN 62304:2006/AC:2008 Medical device software - Software life-cycle processes.</p> <p>EN 62366:2008 Medical devices - Application of usability engineering to medical devices.</p>
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