



Post Authorisation Assessments

Nobilis IB+ND+EDS

Vm 01708/4275

•	12 February 2021	Change in the name of the MAH from Intervet UK Limited to MSD Animal Health UK Limited.
•	20 June 2019	Omission of the second inactivation test from the list of in-process control tests Addition of IPC test for determination of infectivity titre prior to inactivation. Additional production site and IPC test location. Change to final formulation of finished product. Change in the inactivation procedure. Replacement of growth substrate.
•	13 April 2016	To implement MSD logo in the packaging material and update the mock-ups in accordance with the last version of the QRD template. To update the SPC according to the last version of the QRD template.
•	11 November 2013	Changes to the manufacturing process of the active and submission of a new TSE Ph. Eur. Certificate of Suitability.
•	28 March 2012	Change of manufacturer of the active substance
•	22 March 2012	Change of manufacturer of the finished product
•	19 May 2011	Minor change to manufacturing process of an active substance Addition of an in-process control test applied during the manufacture of an active substance
•	06 May 2010	Renewal
•	05 March 2008	Addition of an alternative manufacturing site for quality control testing
•	14 February 2008	Harmonisation of the SPC
•	15 August 2006	Change of legal category from POM to POM-V Changes to the SPC and Product Literature to bring in line with new legislation
•	14 December 2005	Change of address of distributor