Own Brand Labeller Checklist

Minimum Information that needs to be made available to BSI during the Onsite and Offsite assessment. The required information is based on regulatory requirements, NB-MED 2.5.5 and 2.5.1.

SECTION B – Onsite Assessment Checklist (please tick box if documents are available for review)	
Technical Agreement (signed and dated)	
Quality Objectives and Manual, Organisational Structures, Responsibilities, Qualification and Training	
Vigilance (in line with MEDDEV 2.12-1) / Complaint Handling Process	
PMS Process	
Process for Traceability, Corrective and Preventive Actions, Monitoring and Measuring	
Design Procedure for manufactures with full QA certification (must as a minimum cover how the OBL agrees any design changes with the OEM)	
Process for ensuring compliance of labelling and displaying the CE marking	
Procedure for preparing, reviewing and maintaining a Technical File and the associated documents, such as OEM certificates (minimum those mentioned in this form)	
Purchasing process for selection and control of OEM	
Incoming inspection and Batch release process	
Process for registration with the Competent Authority or assigning this process to the EU Rep	
Process for Control of records & documents	
Change notification process to cover notification of significant changes to BSI (NB-MED 2.5.2)	
Management review procedure	
Unannounced Visit process	

SECTION C –Technical Agreement Checklist (please indicate page number)	
OBL Details	
OEM Details	
Identification of devices covered	
OEM needs to maintain his CE approval and notifies of any change or withdrawal	
OEM to provide notification of significant changes / vigilance reports / product recalls and corrective actions taken.	
Documentation sharing between OEM/OBL	
Documentation retention period both OEM and OBL for the products supplied (time, location, access)	
Responsibilities of maintaining the content of the technical files, and design, translation and affixing of labels, IFU and other documents	
Describe the system for advising each party and the Notified Body of any changes to the product or process	

The contents of this document are confidential to BSI Group
The definitive version of this document is only available through the BSI BMS

Identification of the party responsible for Vigilance (e.g. communication of incidents, feedback into CAPA, CA/NB notification, reporting timescale, recall etc.)	
Details of the process for Post market surveillance? (e.g. responsibility, sharing of information, feedback into design etc.)	
Access to OEM Technical documentation for OBL or at least BSI and Competent Authorities	
Access to the OEM location without prior notice by at least BSI and Competent Authorities	

SECTION D – Offsite Documentation Review (please tick box if documents are available for review and submit for review on request)	
OBL Summary Technical File Part A (in line with NB-MED 2.5.1) – Please reference all sections of the OEM's technical documentation which are being relied upon.	
OEM & OBL Product Labels & Instructions For Use	
Copies of the OEM CE Certificates (where applicable include R&TTE, PPE, etc.)	
OBL Draft Declaration of Conformity	
OEM signed Declaration of Conformity	
Last OEM Notified Body QMS Audit Report	
A declaration from the OEM that the supplied devices are not product of an OEM/OBL agreement themselves	
Devices that fall into Rule 13 (Device Drug combinations) – A confirmation from the OEM that a consultation has taken place in the form of the report or report reference number	
For devices utilising tissues / derivatives from TSE susceptible species, confirmation from the OEM that certification has been issued in accordance with Regulation 722/2012	
For IVD Annex II List A products – The OEM notified body batch release authorisation	
For Annex III applications *a copy of the OEM test*	