Requirement[1]	File	ID	Yes/No/N/A
inical Data			
conformity without clinical data Yes 5/EEC and Annex X.1.ld of No 93/42/EEC) must be and based on isk management process xt of the device-body interaction al performance anufacturer. tion of conformity based on performance evaluation, -clinical evaluation in the absence of clinical ly substantiated. t review the manufacturer's justification, the ented and whether or not conformity is demonstrated. 's justification adequate? evaluation, bench testing and pre- adequate to demonstrate sential Requirements? Clinical			
ld include in the technical Yes • Clinical literature ment on the route(s) applied to No • Published data used to affix the "CE" ted make clear whether that . n ained from the published ults of clinical investigations or a Combination of igation data nd shall include an adequateComment route(s) selected and a valency (technical, biological, y if clinical data from similar d			
on Report and. the full clinical data used for CE luded within the technical documentation			
clearly documented the objectives and the scope of the nd specified the clinical ER's [e.g. clinical . y, risks and favourable benefit/risk ratio related to group(s) and indication(s)] to be met			
clearly outlined the performed steps and procedures of ccording to this MEDDIEV (specifically sections 5 to tion given for deviations			
n route			
estigation			
ice antable or class III medical device or an active evice?			
gation is t presented for an 111 MD or an AIMD, has this			

fied by the manufacturer in his . nical evaluation'?			
e is presented for equivalent ical data when taken together with the available pre ent to . demonstrate conformity with the essential safety and performance of the der rmal conditions of use?			
e is presented for equivalent os in either the demonstration of compliance with al requirement . or in the demonstration of s addressing through the means of a specifically estigation(s)?			
e is presented for equivalent devices, is the data the clinical hazards identified in the risk ation(s) will be needed. The objectives of the n(s) should focus on those aspects sufficiently			
nvestigation			
exes of the medical devices Directives (Annex 7 A1MD, relevant standards (EN ISO 14155-1, -2) taken into			
ical investigations			
evant documentation, the following documentation nd reviewed by the Notified body:			
submitted to the Competent Authority or other which grounds for objection were raised .			
" objection"/approval from Competent (if available) or other approval from the relevant , together with any comments made arising from			
mmittee opinion(s) and comments arising from their f all Ethics Committee opinions and any• risings from their reviews			
d dated final report			
cked the following information should be checked by			
from the Competent Authority(ies)[1]			
n Plan (CTP): Is the CIP, used for the clinical ne as that submitted to the Competent Authority?* *should be paid to the number of patients entered, gation(s)(in particular which essential ng addressed, duration of investigation(s) and ort & long term)end points in terms of diagnostic sessment inclusion criteria.*			
as set out in the original CIP, the rationale for non-			

changes to CIP and rationale for any such changes			
vestigation(s) was performed outside the EU, the onstrate that the use of the device (including techniques) and patient population are equivalent to evice will be used within the EU (if relevant).			
nations, have any issues or concerns raised as part of nt of the • medicinal substance by the medicinal or EMEA been considered and/or resolved?			
tigation The report should be reviewed and should information			
d. abstract should be provided, presenting the dy'* vestigation(s); identification of the medical names, models as relevant for complete identification tement indicating whether the investigation(s) was ce with CEN/ISO Standards;objectives; subjects; ation (s) initiation and completion dates, including ation, if applicable; results; conclusions; authors of rt.			
f statement placing the study in the context of the dical device in question and an identification of n the development of the Protocol			
'* ription; summary description of the device and its r with any modifications performed during the			
al investigation plan"* investigation objectives; the investigation design; investigation end points; ethical considerations; nclusion/exclusion criteria; sample size; treatment ion; investigation variables; concomitant s; duration of Follow up; statistical analysis on hypothesis or pass/fail criteria, sample size cal analysis methods.			
n should contain summary information with a alysis and results* gation initiation date; investigation date; the disposition of patients/devices; the clinical investigation analysis to include safety report, including a summary and adverse device events seen in the investigation, n of the severity, treatment required, resolution and estigator of relation to treatment; performance or y sub group analysis for special population; a ssing data, including patients lost to follow up or with in the analysis			

usions'* ance and safety results of the study; the relationship clinical relevance and importance of the results, ight of other existing data and discussion of e of the art"; any specific benefits or special for individual subjects or at risk groups; ally conduct of future studies. ating clinical investigator (if No oal investigator at each centre			
report should be signed off by the			
containing clinical investigation plan, Yes list of investigators and their No other parties involved, list of monitors, N/A. (if applicable), fist of Ethics approval letters.			
clinical investigation (s) data presented			
ass/fail criteria of the investigation(s) been met?			
conclusions of the clinical investigation(s) ce with the identified relevant essential			
n the device labelling substantiated. Yes taken together with the relevant pre-clinical data?			
demonstrated that the risks associated with the use out by the manufacturer, are acceptable when balanced to the patient'			
rformed in a critical and objective manner?			
ata of relevant scientific literature that is currently safety, performance, design characteristics and he form of a written report			
of relevant scientific literature has			
the identification, selection, of relevant publications should be written.			
literature review should be clearly			
that arc relevant to the objective of should be specified			
from recognised scientific shed data should also be taken into account in order bias.			
should state			
nt of the searches of databases or other sources of			
ection/ relevance of the published			
that all relevant references, both urable, have been identified			
n of particular references together with a			

is exclusion.			
of the different stages of literature search. tion, appraisal, No on of hits)			
sented			
hould clearly establish the extent to which the the specific characteristics and. features of the ation.			
les do not directly refer to the device in question, ce with the device, which is the subject of the e same clinical condition or purpose, at the same site ar population (including age, anatomy, physiology); critical performance according to expected clinical ntended use similar conditions of use; have similar operties e.g. tensile strength, viscosity, surface f similar design; use similar deployment methods (if ar principles of operation materials in contact with the same human tissues or eviewed journals			
devices should have similarity inical, technical and biological parameters with the performance,principles of operation and. e are differencesidentified,an assessment and significance these might have on safety and et out"			
be able to demonstrate the adequacy of the data in s of conformity set out in the objective			
ical data should make clear the significance that is attached ces based on a number of factors. These include:			
or's background and expertise in cular device and/or medical procedure No			
conclusions are substantiated by the available data			
e reflects the current medical practice and the d "state of the art" technologies			
e taken from recognised scientific publications and ave been reported			
he published literature is the outcome of a ave followed scientific principles in relation to demonstrable and appropriate endpoints, inclusion and n appropriate and validated number of patients t for an appropriate duration, providing evidence and se incidents, deaths, exclusions, withdrawals and up and identifying an appropriate statistical plan of			

idence should be generated from a clinical trial riate), properly designed cohort/case controlled d case histories or sequential reports conducted by ed experts, whether in relation to the device itself ce. If unpublished data is being included in the ature review will need to weigh the significance that report			
f the literature should contain a critical evaluation of the ical evaluation should:			
n suitably qualified in the relevant field, and by an expert knowledgeable in the "state of the art" te objectivity			
ipption of the medical device, its escription of the intended purpose No and application			
f all the available data considered, nfavourable			
to which the literature relates to the specific eatures of the device being No assessed, taking due of similarity between the device(s) covered by the vice under assessment			
e aspects of the use of the device, including d in the clinical part of No the risk analysis are met ufacturer, and that the device fulfils its intended device			
d hazards, the associated risks and the appropriate tients, medical staff and third parties involved in			
is relevant to the device design, res involved, taking into account No any adverse st-market surveillance, studies, modifications and			
of the methods of weighting of different papers and ds of analysis employed taking into account the he type and duration of study and the heterogeneity of ed within the study			
f the market experience of the same ncluding the results of post-marketing No studies, nce and short- and long-term . adverse events			
lications appropriately cross- luation			
relates to an equivalent device, contain a statement all the relevant No characteristics has been			
with a justification, including an assessment of any ealth from the use No of the device as intended by the probable risks of injury or illness from such USC "state of the art". The conclusions should jectives of the literature review have been met and the evidence necessary to cover all relevant aspects ance*			

nsider the claimed use- indications, contra- actions for use proposed. by the manufacturer.			
on should be signed and dated by the author			
critical evaluation of literature presented by the			
conclusions valid			
gether with the available pre clinical data, rate compliance with the No essential requirements erformance of. the device in question* in the demonstration of compliance with the relevant s or in the demonstration of equivalence that need e means of a specifically designed clinical r normal conditions of use?			
n the device labelling substantiated by the clinical ith the pre-clinical data?			
rformed in a critical and objective manner?			
follow up-the notified body should check and review st market clinical follow up plan:			
presented an appropriate plan for post-market clinical n appropriate guidance?			
nical follow up plan is presented, has this been by the manufacturer?			
an adequate post-market surveillance system in place?			
committed to inform the NB of o their clinical evaluation arising from PMS/PMCF?			
n Making			
uation of clinical data submitted by the manufacturer ether the manufacturer has adequately			
d, the intended, characteristics and to clinical aspects			
ysis and estimated the undesirable			
s of documented justification that ble when weighed against the No intended benefits			
fit/risk presented in the clinical			
cterisation of the clinical performance of the device facturer and the No expected benefits for the patient			
f identified. hazards to be addressed. through l data			
on of the associated risks for each identified hazard severity of the hazard;. racterising the probability of n (or health impairment or loss of benefit of the with rationale)			
cceptability of risks in relation to rd			