Medical Devices Legislation
Guide to EC and EU Documents

This document provides a guide to papers shared by the European Commission, either publicly through their online archive portal or in an emailed response to a research request. Information about each item can be found in the following format:

FILE NAME	DETAILS
DATE	
WHO/WHAT	
HOW IT WAS ACCESSED/ACQUIRED	

The file name also serves as a hyperlink to the document in question.

File names were inherited from the Commission and have not been altered.

Where multiple potential dates could be associated with a document, the date which best reflects their moment of creation has been chosen.

Contents

This resource is a contribution to the Everyday Cyborgs 2.0 project, based at the University of Birmingham. You can learn more about the project at our website: https://blog.bham.ac.uk/everydaycyborgs/

The project is generously supported by a Wellcome Trust Investigator Award in Humanities and Social Sciences 2019-2024 (Grant No: 212507/Z/18/Z).

This resource was created by Dr Dominic J. Berry, in collaboration with Prof. Muireann Quigley, Dr Joe Roberts, Dr Rachael Dickson, and Dr Laura Downey.

1. Introduction to these materials

There are 6 main types of document in this collection:

1.1 Proceedings

The most common kind of paper in this collection is *Outcomes of the Proceedings of Working Parties* established to debate and draft each new Directive. These documents record the results of discussions in Working Party meetings, including the questions raised, suggestions made, points of clarification sought, and so on. Unfortunately they are not minutes of these meetings, and so they reveal very little about what the sticking points of discussion might have been, or the assumptions and interests motivating suggestions. These Proceedings also become denser over time - as the drafts of Articles and Annexes become fuller and more established - leading to greater amounts of repetition between documents (and eventually larger full drafts, which often seem to accumulate all of the various points already recorded up to that stage). Nevertheless, these documents can reveal important branching moments, as when it is debated (in a discussion of a draft Directive for *in vitro* diagnostic medical devices) whether or not to create an entirely new Directive dedicated to a further range of devices incorporating human tissues. More generally, these documents expose how different parts of these pieces of legislation were discussed and drafted at different times; potentially revealing logics in their construction that are otherwise hard to perceive.

1.2 Delegation Notes

Less common, but very instructive, are notes prepared by individual national delegations and circulated to these Working Parties. These tend to be focussed on matters of particular concern, and often go into detail about the questions raised by a country or the justifications for their interests. The reception of these documents – as recorded in Working Party proceedings - can also suggest national alignments and frictions.

1.3 Commission Notices

Aside from the activities of the various Working Parties, the Commission also produces other relevant documents, though in smaller numbers. Most significant are the proposals for the creation of these various Working Parties, helping to define their scope, explain some overall motivations and considerations, and sometimes pull together contextual elements to explain how these new Directives fit within longer term or broader legislative agendas.

1.4 Parliament Requests

Another fairly common kind of paper records interactions between the European Parliament and drafts of the Directive, as submitted to Parliament by the Working Party. These sometimes incorporate the concerns raised by Parliamentary members, and of course list

many of the requested changes. Even here, however, not all requested changes are listed, rather only those which the Commission is comfortable incorporating into the draft.

1.5 Parliament/Council Notices

The European Parliament also produces its own documents, though those collected here are highly functional, primarily concerned with organising sessions of Parliament, scheduling readings of proposals, recording the dates of related meetings, and recording when Parliament has determined that a Directive should be submitted for publication (i.e., made European law).

1.6 Directives

Potentially the least interesting documents are copies of these final full Directives as published in the *Official Journal of the European Communities* (later *Union*). These are readily available online. They have not been removed from this collection in order to retain its overall sense of completeness, and to reflect the shared provenance of many of these files, supplied to us as a packet by the archives of the European Commission.

Finally we provide the following pointers to help users avoid being misled by this collection:

- Please remember that these are merely the documents we received after making a very general request to the Archives of the European Commission. Future researchers asking more pointed questions, or with direct access to the Commission Archives, would no doubt find a great many more relevant documents.
- This means that if a type of document has been introduced here as 'abundant' and another type described as 'less common', these statements are made in relation to the collection received, NOT the overall state of the Commission Archives, or the rate of production of these documents during the actual Directive drafting process. Again, getting insights into that process – and learning where the best records of Directive debate and discussion took place – would be a matter for a longer and more sustained research project.
- As for connecting these documents to the archival sources that produced them, we here copy the contents of an email received from the central Archives, explaining their provenance (received 25/3/2021 from Francesca Davanzo):

> The Council Archives are organized according to the different stages of the EU Legal Basis (for more details Archives - Consilium (europa.eu)). In the search page you also find the detailed inventories until 1989.
>
> Each fond is then organized by year and includes the legal acts adopted by the Council, the Coreper and Council meetings, the European Council meetings.
>
> The files you asked for are part of the Legal Acts. Such files normally include all documents produced by the Council in respect to the adoption of the legal act: the Commission proposal, the results of the Working Party/ies meetings, the

discussions at Coreper and Council level (if any). The files can include the contribution from the European Parliament and the Economic and Social committee (if any).

The reference for the files you received are:

- CM2 (Fond) 1990 (Sub-fond) .440 (File number) - Directive 90/385/CEE du Conseil du 20.06.1990 concernant le rapprochement des législations des États membres relatives aux dispositifs médicaux implantables actifs.
- CM2 1993.429 - Directive 93/42/CEE du Conseil du 14.06.1993 relative aux dispositifs médicaux
- CM4 1.322 - Directive 98/79/CEE DU PARLEMENT EUROPEEN ET DU CONSEIL DU 27.10.1998 RELATIVE AUX DISPOSITIFS MEDICAUX DE DIAGNOSTIC IN VITRO

2. Papers relating to a Directive on active implantable medical devices (which became 90/385/EEC)

1988 - Proposal for a COUNCIL DIRECTIVE on the approximation of the laws of the Member States relating to active implantable electromedical equipment 6/12/1988 Presented by the Commission	Full draft of the proposal for a Directive on active implantable electromedical equipment. 660 pages. Includes a short discussion of device categorisation. Worries that regulation is not keeping pace with innovation. Focus on technology as means for creating better living as well as economic security. Recognises a different for implants in terms of their energy source. CENELEC standard being developed for cardiac stimulators is seen as offering a blueprint for all future electrical standards in this area. "A large part of its technical content applies to implants as a whole for which it may be easier and faster to prepare draft European standards". Includes flow diagrams of potential certification processes. Software not 'in' an instrument is excluded from scope.
Archives of the European Commission website	

st04551.en89 1/2/1989 Proceedings of working party on electromedical equipment	Outcome of proceedings of Working Party on electromedical equipment. Discussing proposal for a Directive on active implantable electromedical equipment. 6 pages. Some argument that safety has been over-emphasised to the marginalisation of health protection and the effectiveness of technology. Promised work is underway to expand on the standard recently developed for the cardiac defibrillator.
Received from European Council Archives 19/3/2021 – Folder 90_385	

st04846.en89 15/2/1989 Note for the Working Party from the UK delegation	Note from UK delegation on proposed Directive for active implantable electromedical equipment. 8 pages. UK wants to maintain active/passive distinction. Wants to consider excluding the artificial heart from this Directive, and feels that national authorities should retain right of control over devices that result in death if they malfunction. Also wants greater time to be spent distinguishing drugs and devices. Is also keen to ensure that 'prototypes' are not easily excluded, because in some areas of industry these make up the largest part of the actual market.
Received from European Council Archives 19/3/2021 – Folder 90_385	

st05297.en89 2-3/3/1989 Proceedings of working party on electromedical equipment	Outcome of proceedings of Working Party on electromedical equipment. Discussing proposal for a Directive on active implantable electromedical equipment. 6 pages. Initial definition of the scope of the Directive. Articles 1-4. Other countries agreeing on the removal of the artificial heart from scope. Likewise agreement with the UK that sections concerning prototypes need to be rethought so as not to exclude such a large collection of devices from scope.
Received from European Council Archives 19/3/2021 – Folder 90_385	

st05311.en89 14/3/1989 Note for the Working Party from the Spanish delegation	Note from Spanish delegation on proposed Directive for active implantable electromedical equipment. 6 pages. A few different points raised. Want to see an Article added on rapid exchange of info whenever a serious and urgent hazard is identified.
Received from European Council Archives 19/3/2021 – Folder 90_385	

st05498.en89	Directive on active implantable electromedical equipment has been subject to consultation with the European Parliament and the Economic and Social Committee.
15/3/1988	
Monthly list of Acts adopted by means of the Council's written procedure	18 pages. Only Announcement number 11 concerns this topic.
Received from European Council Archives 4/3/2021	

Report 53-89 (1)	Report on the Commission proposal for a Directive concerning active implantable electromedical equipment.
3/4/1989	
European Parliament session document	7 pages. Includes timeline of sittings of Parliament that have considered this proposal. Also meetings of the Committee dedicated to it. Incorporates a few amendments concerning definition of the devices covered, and notification process.
Received from European Council Archives 4/3/2021	

Report 53-89 (2)	Report on the Commission proposal for a Directive concerning active implantable electromedical equipment.
3/4/1989	
European Parliament session document	2 pages. Includes an explanatory statement concerning the proposed Directive. Laying out principles for harmonization and conformity procedures.
Received from European Council Archives 4/3/2021	

st05887.en89 6/4/1989 Note for the Working Party from the UK delegation	Note from UK delegation on proposed Directive for active implantable electromedical equipment. 8 pages. Lists a series of proposed amendments to the current draft. Interested in demarcating between medical products and devices. Adding further requirements for high-risk devices. Amongst others.
Received from European Council Archives 19/3/2021 – Folder 90_385	

st05916.en89 6-7/4/1989 Proceedings of working party on electromedical equipment	Progress report of the Working Party on proposed Directive for active implantable electromedical equipment. 16 pages. Lists all of the requested additions thus far, including many proposed by the UK.
Received from European Council Archives 19/3/2021 – Folder 90_385	

Report 53-89 (3) Resolution 12.4.1989 16/5/1989 Official Journal of the European Communities	Amendments to the proposal for a Directive on active implantable electromedical equipment. 3 pages. Amendments requested by Parliament.
Received from European Council Archives 4/3/2021	

st08054.en89 11/7/1989 Proceedings of working party on electromedical equipment	Newly drafted Annex 1 for Working Party on active implantable electromedical equipment. 6 pages. Annex 1 is concerned with essential safety requirements.
Received from European Council Archives 19/3/2021 – Folder 90_385	

st08055.en89 11/7/1989 Proceedings of working party on electromedical equipment	Newly drafted Annex 5 for Working Party on active implantable electromedical equipment. 4 pages. Annex concerns clinical evaluation.
Received from European Council Archives 19/3/2021 – Folder 90_385	

st07925.en89 14/7/1989 Proceedings of working party on electromedical equipment	Newly drafted Annex 2 for Working Party on active implantable electromedical equipment. 22 pages. This new version breaks the Commission's original Annex 2 into 6 sperate Annexes.
Received from European Council Archives 19/3/2021 – Folder 90_385	

st08212.en89 24-25/7/1989 Proceedings of working party on electromedical equipment	Discussion of the procedure for assessing conformity in the proposed Directive on active implantable electromedical equipment. 6 pages. Annexe II updated concerning monitoring of the conformity of equipment. Also Annexe 6 on specialist/custom devices.
Received from European Council Archives 19/3/2021 – Folder 90_385	

st08222.en89 24-25/7/1989 Proceedings of working party on electromedical equipment	Newly drafted Article 1 for Working Party on active implantable electromedical equipment. 4 pages. Annotated with the changes incorporated and some of the reasoning. Someone has raised the question of 'partially implanted devices'.
Received from European Council Archives 19/3/2021 – Folder 90_385	

1989 - BAC-COM(1989)0418 COM(1989) Amendment to the proposal for a Council Directive of the laws of the member states relating to active implantable electromedical equipment 23/8/1989 Presented by the Commission	Amendment to the proposal for a Directive on active implantable electromedical equipment. 34 pages. Explains the proposal is being reviewed in light of European Parliament's discussion of the initial proposal. Very short document.
Archives of the European Commission website	

st08389.en89 30/8/1989 Letter from Commission to President of the Council of the European Communities	Amended proposal for a Directive on active implantable electromedical equipment. 8 pages. Incorporates some of the changes requested after a session of the European Parliament.
Received from European Council Archives 19/3/2021 – Folder 90_385	

st08216.en89 4-5/9/1989 Note for the Working Party from the UK delegation	Note from UK delegation on proposed Directive for active implantable electromedical equipment. 6 pages. Includes suggested text for a number of the Articles. UK is now also using the phrase 'Active Implantable Medical Devices'. Also words stating "Software packages that do not form part of the device are excluded from this definition".
Received from European Council Archives 19/3/2021 – Folder 90_385	

st08528.en89 4-5/9 and 11/9/1989 Proceedings of working party on electromedical equipment	New FULL DRAFT of the Directive for Working Party on active implantable electromedical equipment. 52 pages. Annotated with the changes incorporated and some of the reasoning. UK proposing high/medium/low risk classifications. France wants to ensure non-EC devices can still be shown at trade fairs even if they are not yet available for purchase in the EC. UK drafts an additional statement regarding post-market surveillance, in cases of high risk devices. Delegation 'D' (Germany? Denmark?) wants beneficial effects to outweigh risks according to a scale – but Commission is not keen on this idea.
Received from European Council Archives 19/3/2021 – Folder 90_385	

st08580.en89 15/9/1989 Note for the Working Party from the UK delegation	Note from UK delegation on proposed Directive for active implantable electromedical equipment. 10 pages. Suggestions for Annexes I and X. Concerning essential requirements and high risk devices.
Received from European Council Archives 19/3/2021 – Folder 90_385	

st09194.en89 25/9/1989 Proceedings of working party on electromedical equipment	New text for Articles 2 and 7 of the Directive for Working Party on active implantable electromedical equipment. 42 pages. Annotated with the changes incorporated and some of the reasoning.
Received from European Council Archives 19/3/2021 – Folder 90_385	

st09561.en89 9/11/1989 Note for the Working Party from the Netherlands delegation	Note from Netherlands delegation on proposed Directive for active medical implantable devices. 4 pages. Suggested amendments for Annex I, on essential requirements.
Received from European Council Archives 19/3/2021 – Folder 90_385	

st09899.en89 16-17/11/1989 Proceedings of working party on electromedical equipment	New FULL DRAFT of the Directive for Working Party on active implantable electromedical equipment. 60 pages. UK is still worried about distinguishing between medicines and devices. Proposes 3 risk categories, but there is evidence of opposition to them. UK is also interested in including statements as to the usefulness of a device in its assessment.
Received from European Council Archives 19/3/2021 – Folder 90_385	

st10713.en89 11/12/1989 Note for the Working Party from the Greek delegation	Note from Greek delegation on proposed Directive for active medical implantable devices. 7 pages. They think that the Annexes need to be re-written to reduce duplications between them.
Received from European Council Archives 19/3/2021 – Folder 90_385	

st10823.en89 15/12/1989 Draft Summary Record of the 1412th meeting of the Permanent Representatives Committee	Amended proposal for a Directive on active implantable electromedical equipment. 4 pages. The 'GR' delegation (Greek?) requests two amendments which are rejected by the Commission because other delegations do not support them. Concerns items manufacture to order.
Received from European Council Archives 19/3/2021 – Folder 90_385	

st10957.en89 15/12/1989 Report from the Permanent Representative Committee	A progress report and the latest draft of the Directive on active implantable electromedical devices. 66 pages. UK delegation has made specific reservations on 2 points: (1) Extending application of Article 2 to custom-made devices. (2) The provisions of Annex 6 on custom-made devices and devices intended for clinical investigation: the UK would prefer more stringent provisions.
Received from European Council Archives 19/3/2021 – Folder 90_385	

st04324.en90 24/1/1990 Item note from the General Secretariat to the Permanent Representatives Committee	Item note on the adoption of a Directive for active implantable medical devices. 8 pages. Some suggestions from the Working Party of Legal/Linguistic Experts. Also the UK wants level of conformity evaluation to track a device's risk level.
Received from European Council Archives 19/3/2021 – Folder 90_385	

st04071.en90 26/1/1990 Draft Common Position for the Council	FULL DRAFT of the proposed Directive on active implantable medical devices, including Annexes. 98 pages.
Received from European Council Archives 19/3/2021 – Folder 90_385	

st04071-ad01.en90 22/2/1990 Common Position adopted by the Council	Common Position adopted by the Council, on active implantable medical devices. 4 pages. Includes the Council's reasons. Also provides for a warning system and a standing advisory committee.
Received from European Council Archives 19/3/2021 – Folder 90_385	

st05475.en90 16/3/1990 Commission to European Parliament	Statement from the Commission to the European Parliament on the Directive for active implantable medical devices. 10 pages. Explains how the common position was changed after Parliament's requested amendments. Much to do with devices for research purposes, and the assumed/tacit approval process.
Received from European Council Archives 19/3/2021 – Folder 90_385	

Report 82-90 3/4/1990 European Parliament session document	Recommendation on the common position for a Directive on active implantable medical devices. 7 pages. Includes timeline of sittings of Parliament that have considered this proposal. Also meetings of the Committee dedicated to it. Particular attention to measures necessary for devices in clinical investigations and more on definitions.
Received from European Council Archives 4/3/2021	

st06911.en90 5/6/1990 From Working Party of Economic Counsellors to Permanent Representative Committee	Report of discussion in Working Party of Economic Counsellors following suggested changes to the Directive from the European Parliament. 4 pages. Ultimately prepared to proceed to publishing the Directive.
Received from European Council Archives 19/3/2021 – Folder 90_385	

st06997.en90 7/6/1990 Note for the Working Party from the French delegation	Small amendment request from French delegation regarding wording of Directive on active implantable medical devices. 2 pages. Concerns responsibilities of medicinal product competent authorities in cases where devices incorporate medicinal products.
Received from European Council Archives 19/3/2021 – Folder 90_385	

st06968.en90 12/6/1990 Council Directive	FULL DRAFT of the Council's adopted Directive on active implantable medical devices. 64 pages.
Received from European Council Archives 19/3/2021 – Folder 90_385	

st07193.en90 14/6/1990 From Permanent Representatives Committee to Internal Market Council Meeting	Adoption of the new Directive on active implantable medical devices. 2 pages. Text agreed. Recommends its publication.
Received from European Council Archives 19/3/2021 – Folder 90_385	

1989 - BAC-COM(1990)0247 COM(1990)247 re-examined proposal on implantable medical devices COM (88) 717 14/6/1990 Presented by the Commission	Re-examination of the proposal for a Directive on active implantable medical devices. 47 pages. Includes a short explanatory memorandum. Proposal has received further comments in the European Parliament as of May 1990. This re-examined version incorporates Parliament's suggested amendments where the Commission agrees to them. Very short document.
Archives of the European Commission website	

st07366.en90 15/6/1990 From Commission to President of the Council	Materials enclosed with a copy of the Directive on active implantable medical devices. 8 pages. Includes Commission's opinion on European Parliament amendment which was not accepted.
Received from European Council Archives 19/3/2021 – Folder 90_385	

Report 82-90 Decision 16.5.1990 18/6/1990 Official Journal of the European Communities	Decision on the common position for a Directive on active implantable electromedical equipment. 2 pages.
Received from European Council Archives 4/3/2021	

Written Question 728-93	Written question No 728/93 by Mr José Valverde López. "Is the Commission aware of the chaotic situation of the 12 Member States with regard to a matter which is of such importance for the health and safety of patients, namely the general failure to implement the directive on active implantable medical devices (Directive 90/385/EEC)?"
3/11/1993	
Official Journal of the EU	
Received from European Council Archives 4/3/2021	

CELEX_32007L0047_EN_TXT	Amendments to Directives 90/385/EEC, 93/42/EEC, and 98/8/EC. 35 pages. Includes clarification as to when software constitutes a medical device. Updating and harmonising some language across different Directives. Also incorporates lessons learned from a number of years of device regulation.
21/9/2007	
Official Journal of the EU	
Received from European Council Archives 4/3/2021	

3. Papers relating to a Directive on medical devices (which became 93/42/EEC)

st07954.en91 30/8/1991 From Commission to President of the Council of the European Communities	Commission proposal for a Directive on medical devices (other than non-invasive, active implantable and *in vitro* devices), presented to the President of the Council of the European Communities. 110 pages. Emphasises the scale of the market, and the pace of innovation needing an appropriate legislative framework. Heavily based on the active implantable medical devices Directive.
Received from European Council Archives 19/3/2021 – Folder 93_42	

st09460.en91 11/11/1991 Proceedings of working party on medical devices	Outcome of proceedings of Working Party on medical devices (other than non-invasive, active implantable and *in vitro* devices). Discussing proposal for a Directive. 4 pages. Some points raised following first reading of the initial draft proposal.
Received from European Council Archives 19/3/2021 – Folder 93_42	

st04525.en92 31/1/1992 Proceedings of working party on medical devices	Outcome of proceedings of Working Party on medical devices (other than non-invasive, active implantable and *in vitro* devices). Discussing proposal for a Directive, focussed on Articles 9-14. 6 pages. Some points raised following reading of the initial draft proposal.
Received from European Council Archives 19/3/2021 – Folder 93_42	

st04608.en92 6/2/1992 Note for the Working Party from the UK delegation	Note from UK delegation on proposed Directive for medical devices (other than non-invasive, active implantable and *in vitro* devices). 14 pages. Suggesting amendments to wording in Annex 1 (concerning essential requirements).
Received from European Council Archives 19/3/2021 – Folder 93_42	

st05998.en92 15/4/1992 Note for the Working Party from the UK delegation	Note from UK delegation on proposed Directive for medical devices (other than non-invasive, active implantable and *in vitro* devices). 8 pages. Suggesting amendments to Annex a (concerning essential requirements) and Annex II (concerning the issue of bioavailability). Particularly products that achieve action by chemical means. Again the UK delegation is concerned about muddying the distinction between devices and medicines. They present some examples of chemicals that – if the current draft was adopted – would have to become considered devices. They are interested in removing bioavailability as a concept, and also to ensure custom devices are fully covered.
Received from European Council Archives 19/3/2021 – Folder 93_42	

st06228.en92 28/4/1992 Proceedings of working party on medical devices	Outcome of proceedings of Working Party on medical devices (other than non-invasive, active implantable and *in vitro* devices). Discussing proposal for a Directive, focussed on Annexes, 1 8 and 10. 6 pages. First full reading of the proposal is now complete.
Received from European Council Archives 19/3/2021 – Folder 93_42	

Report 178-92 28/4/1992 European Parliament session document	Report on the Commission proposal for a Directive concerning medical devices. 58 pages. Includes timeline of sittings of Parliament that have considered this proposal. Also meetings of the Committee dedicated to it. Particular attention to conformity assessment. Long list of amendments to be incorporated into the proposed Directive. Further clarification as to the significance of software for medical devices. Explanation of the classification of devices into four groups according to how vulnerable they make the human body. Also briefly discuss another rationale for their classification, based on how much contact they have with the body and whether organs are involved.
Received from European Council Archives 4/3/2021	

st08107.en92 14-15/7/1992 Proceedings of working party on medical devices	Outcome of proceedings of Working Party on medical devices (other than non-invasive, active implantable and *in vitro* devices). Discussing proposal for a Directive, focussed on Articles 1-14. 22 pages. Some annotations concerning the changes made.
Received from European Council Archives 19/3/2021 – Folder 93_42	

st08171.en92	Note from Dutch delegation on proposed Directive for medical devices (other than non-invasive, active implantable and *in vitro* devices).
22/7/1992	
Note for the Working Party from the Dutch delegation	2 pages. Interested in the difficulty of manufacturer stating intended performance. Some devices made *for* a hospital, others *for* the home, and so different performances might be expected. They think clarification of performance can help, giving the example of wheelchairs in the Netherlands.
Received from European Council Archives 19/3/2021 – Folder 93_42	

st08172.en92	Note from Greek delegation on proposed Directive for medical devices (other than non-invasive, active implantable and *in vitro* devices).
22/7/1992	
Note for the Working Party from the Greek delegation	6 pages. Mainly concerned with radiation.
Received from European Council Archives 19/3/2021 – Folder 93_42	

st08345.en92	Commission writing to the President of the Council of the European Communities following discussion in the European Parliament of a new Directive for medical devices (other than non-invasive, active implantable and *in vitro* devices).
28/7/1992	
From Commission to President of the Council of the European Communities	26 pages. Commission is amending its proposal in light of Parliament's suggested amendments, offered at Parliament's first reading on 14/5/1992. The Commission has accepted 36 of the 62 amendments approved by Parliament. The modifications are listed here.
Received from European Council Archives 19/3/2021 – Folder 93_42	

st08538.en92 7/9/1992 Proceedings of working party on medical devices	Outcome of proceedings of Working Party on medical devices (other than non-invasive, active implantable and *in vitro* devices). Discussing proposal for a Directive, focussed on Articles 15-24. 12 pages. Some annotations concerning the changes made.
Received from European Council Archives 19/3/2021 – Folder 93_42	

st08623.en92 10/9/1992 Note for the Working Party from the German delegation	Note from German delegation on proposed Directive for medical devices (other than non-invasive, active implantable and *in vitro* devices). 2 pages. On the wording for a safety principle.
Received from European Council Archives 19/3/2021 – Folder 93_42	

st08755.en92 17/9/1992 Proceedings of working party on medical devices	Outcome of proceedings of Working Party on medical devices (other than non-invasive, active implantable and *in vitro* devices). Discussing proposal for a Directive, focussed on Annex 1. 8 pages. Some annotations concerning the changes made.
Received from European Council Archives 19/3/2021 – Folder 93_42	

st09120.en92 5-6/10/1992 Proceedings of working party on medical devices	Outcome of proceedings of Working Party on medical devices (other than non-invasive, active implantable and *in vitro* devices). Discussing proposal for a Directive, focussed on Annexes 1-8, and 10. 36 pages. More new sections added following Working Party deliberations, including some explanatory annotations.
Received from European Council Archives 19/3/2021 – Folder 93_42	

st09513.en92 23/10/1992 Progress report from working party on medical devices	FULL DRAFT of proposed new Directive on medical devices (other than non-invasive, active implantable and *in vitro* devices). 126 pages. Includes some annotations. The UK is still pushing for greater distinction between devices and chemicals. This document amalgamates many of the previously shared Working Party proceedings documents.
Received from European Council Archives 19/3/2021 – Folder 93_42	

st10136.en92 11/11/1992 Note for the Working Party from the Irish delegation	Note from Irish delegation on proposed Directive for medical devices (other than non-invasive, active implantable and *in vitro* devices). 4 pages. Focussed on Article 10. They are concerned that including all Class I devices within the scope of devices where recording and evaluation are to be done in a centralised manner will cause too great a strain on their institutions. Not least because "It is fair to say that Ireland will be starting its Medical Device Vigilance System from scratch."
Received from European Council Archives 19/3/2021 – Folder 93_42	

st10104.en92 11-12/11 and 18-19/11/1992 Proceedings of working party on medical devices	Outcome of proceedings of Working Party on medical devices (other than non-invasive, active implantable and *in vitro* devices). Discussing proposal for a Directive, focussed on Annexes 1, 9 and 11. 14 pages. Some annotations concerning the changes made.
Received from European Council Archives 19/3/2021 – Folder 93_42	

st10334.en92 18-19/11/1992 Proceedings of working party on medical devices	Outcome of proceedings of Working Party on medical devices (other than non-invasive, active implantable and *in vitro* devices). Discussing proposal for a Directive, focussed on definitions and scope. 12 pages. Continued discussion of the drug/device problem.
Received from European Council Archives 19/3/2021 – Folder 93_42	

st10563.en92 3/12/1992 Progress report from working party on medical devices	FULL DRAFT of proposed new Directive on medical devices (other than non-invasive, active implantable and *in vitro* devices). 136 pages. Some annotations concerning the changes made.
Received from European Council Archives 19/3/2021 – Folder 93_42	

st10742.en92 3/12/1992 Progress report from working party on medical devices	Report on proceedings of Working Party on medical devices (other than non-invasive, active implantable and *in vitro* devices). Discussing proposal for a change to the scope of the Directive, to exclude human tissue. 10 pages. UK is also still pushing for exclusion of chemical means from devices.
Received from European Council Archives 19/3/2021 – Folder 93_42	

st11019.en92 10/12/1992 Progress report from working party on medical devices	Report on proceedings of Working Party on medical devices (other than non-invasive, active implantable and *in vitro* devices). Discussing proposal for a change to the scope of the Directive following meeting of the Committee of Permanent Representatives. 12 pages. Non-viable tissues will remain in scope. This document includes new drafts of the Annexes.
Received from European Council Archives 19/3/2021 – Folder 93_42	

st11116.en92 17-18/12/1992 Minutes of 1634th Council Meeting (Internal Market)	Minutes of 1634th Council Meeting (Internal Market), agreeing that the new Directive should be accepted at a forthcoming Council meeting. 20 pages (only a couple relating to this Directive).
Received from European Council Archives 19/3/2021 – Folder 93_42	

st04433.en93 29/1/1993 Report from General Secretariat of the Council	Report from General Secretariat of the Council to Permanent Representatives Committee, forwarded for approval. 10 pages.
Received from European Council Archives 19/3/2021 – Folder 93_42	

st04327.en93 1/2/1993 Adopted Position on Directive Medical Devices	FULL TEXT of the adopted position for a Directive concerning medical devices (other than non-invasive, active implantable and *in vitro* devices). 136 pages.
Received from European Council Archives 19/3/2021 – Folder 93_42	

st04587.en93 3/2/1993 "A" Item note to the Council	Forwarding the text of the Common Position on medical devices (other than non-invasive, active implantable and *in vitro* devices), including statements for the Council minutes. 8 pages.
Received from European Council Archives 19/3/2021 – Folder 93_42	

st04641.en93 8/2/1993 Draft Minutes of 1640th Council Meeting (internal market)	Draft Minutes of 1640th Council Meeting (internal market), incorporating notice of the adoption of a Directive on medical devices (other than non-invasive, active implantable and *in vitro* devices). 8 pages (only 1 concerning this Directive).
Received from European Council Archives 19/3/2021 – Folder 93_42	

st04327-re01ad01.en93 9/2/1993 Council's Reasons	Council's Reasons for adopting the Common Position on Directive Concerning Medical Devices (other than non-invasive, active implantable and *in vitro* devices). 6 pages. An additional proposal for the creation of a device register is also dismissed, as this function would be covered by a reporting system.
Received from European Council Archives 19/3/2021 – Folder 93_42	

Recommendation 88-93 17/3/1993 European Parliament session document	Recommendation of the Committee on the adoption of a directive on medical devices. 5 pages. Includes timeline of sittings of Parliament that have considered this proposal. Also meetings of the Committee dedicated to it. Particular attention being given to devices that administer a medicinal product.
Received from European Council Archives 4/3/2021	

st06831.en93 25/5/1993 Note from General Secretariat of the Council	Note from General Secretariat of the Council to Permanent Representatives Committee. 2 pages. Suggested improved wording for integrated medicines and devices.
Received from European Council Archives 19/3/2021 – Folder 93_42	

st07274.en93 11/6/1993 Note from Commission to Council	Acceptance of the proposed improved wording for integrated medicines and devices. 8 pages.
Received from European Council Archives 19/3/2021 – Folder 93_42	

Recommendation 218-93	Recommendation of the Committee on the adoption of a directive on medical devices.
1/7/1993	
European Parliament session document	6 pages. Includes timeline of sittings of Parliament that have considered this proposal. Also meetings of the Committee dedicated to it. Particular attention to conformity assessment.
Received from European Council Archives 4/3/2021	

4. Papers relating to a Directive on in vitro diagnostic medical devices (which became 98/79/EC)

st07007.en95 19/4/1995 Commission to Council	Proposal from European Commission to the Council of the European Union to create a Directive on *in vitro* diagnostic medical devices. 2 pages.
Received from European Council Archives 16/8/2021 – Folder 98 79	

st04325.en96 16/1/1996 Note for the Working Party from the French delegation	Note from French delegation on proposed Directive for *in vitro* medical devices. 9 pages. French delegation do not believe the 'new approach' to Directives, even if adapted, is yet suitable for dealing with the kinds of safety and ethical concerns they perceive in this Directive. They are particularly worried about reagents. "Medical devices wholly or partly of human origin can hardly be treated in the same way as ordinary goods, because their main constituent, or one of their constituents, is outside the field of commerce." They consider the medical products Directive to be a better starting point for devices incorporating human materials.
Received from European Council Archives 16/8/2021 – Folder 98 79	

st04789.en96 22-23/1/1996 Proceedings of working party on *in vitro* medical devices	Outcome of proceedings of Working Party on *in vitro* medical devices. Discussing proposal for a Directive, focussed on Articles 1, 2 and Annex 1. 13 pages. Some annotations concerning the changes made.
Received from European Council Archives 16/8/2021 – Folder 98 79	

Report 31-96 9/2/1996 European Parliament session document	Report on the Commission proposal for a Directive concerning *in vitro* diagnostic medical devices. 47 pages. Includes timeline of sittings of Parliament that have considered this proposal. Also meetings of the Committee dedicated to it. Wide range of amendments.
Received from European Council Archives 16/8/2021 – Folder 98 79	

st05284.en96 20-21/2/1996 Proceedings of working party on *in vitro* medical devices	Outcome of proceedings of Working Party on *in vitro* medical devices. Discussing proposal for a Directive, focussed on Annex 1. 10 pages. Some annotations concerning the changes made.
Received from European Council Archives 16/8/2021 – Folder 98 79	

st05658.en96 5-6/3/1996 Proceedings of working party on *in vitro* medical devices	Outcome of proceedings of Working Party on *in vitro* medical devices. Discussing proposal for a Directive, focussed on Articles 1, 2 and Annex 1. 10 pages. Some annotations concerning the changes made.
Received from European Council Archives 16/8/2021 – Folder 98 79	

st05828.en96 12/3/1996 Contribution from Council's Legal Service	The Working Party had asked the Council's Legal Service team for clarification on a few aspects of the proposed Directive in *in vitro* medical devices. 6 pages. One question concerns the distinction between 'putting into service' and 'placing on the market'.
Received from European Council Archives 16/8/2021 – Folder 98 79	

st08664.en96 13-14/6 and 24/6/1996 Proceedings of working party on *in vitro* medical devices	Outcome of proceedings of Working Party on *in vitro* medical devices. Discussing proposal for a Directive, focussed on all Articles apart from Article 20. 20 pages. Some annotations concerning the changes made. More discussion about concerns surrounding human tissue.
Received from European Council Archives 16/8/2021 – Folder 98 79	

st05816.en96 14/3/1996 Information note from the Council	Outcome of European Parliament's first reading of the draft proposed Directive on *in vitro* medical devices. 23 pages (blank from page 4 onward). There were 78 tabled amendments, of which 50 have been adopted.
Received from European Council Archives 16/8/2021 – Folder 98 79	

st06148.en96 18-19/3/1996 Proceedings of working party on *in vitro* medical devices	Outcome of proceedings of Working Party on *in vitro* medical devices. Discussing proposal for a Directive, focussed on Annex 1. 11 pages. Some annotations concerning the changes made.
Received from European Council Archives 16/8/2021 – Folder 98 79	

st07018.en96 22-23/4/1996 Proceedings of working party on *in vitro* medical devices	Outcome of proceedings of Working Party on *in vitro* medical devices. Discussing proposal for a Directive, focussed on Articles 1 and 2. 20 pages. Some annotations concerning the changes made.
Received from European Council Archives 16/8/2021 – Folder 98 79	

st11142.en96 21/10/1996 Proceedings of working party on *in vitro* medical devices	Outcome of proceedings of Working Party on *in vitro* medical devices. Discussing proposal for a Directive, focussed on all Article 19 and Annexes 2,4, and 8. 17 pages. Some annotations concerning the changes made.
Received from European Council Archives 16/8/2021 – Folder 98 79	

st12236.en96 15/11/1996 Proceedings of working party on *in vitro* medical devices	Outcome of proceedings of Working Party on *in vitro* medical devices. Discussing proposal for a Directive, focussed on Article 19. 8 pages. Some annotations concerning the changes made. Belgium, France and the UK push for a separate Directive on human tissue.
Received from European Council Archives 16/8/2021 – Folder 98 79	

st12804.en96 17/12/1996 From the Council to the Working Party on Economic Questions	FULL DRAFT of proposed Directive on *in vitro* medical devices. 101 pages. Some annotations concerning the changes made.
Received from European Council Archives 16/8/2021 – Folder 98 79	

st05283.en97 13/1/1997 Proceedings of working party on *in vitro* medical devices	Outcome of proceedings of Working Party on *in vitro* medical devices. Discussing proposal for a Directive, focussed on Articles 1, 2, 3 and 19. 14 pages. Some annotations concerning the changes made. Further discussion over 'putting into service' versus 'made available'.
Received from European Council Archives 16/8/2021 – Folder 98 79	

st06280.en97 17/2/1997 Proceedings of working party on *in vitro* medical devices	Outcome of proceedings of Working Party on *in vitro* medical devices. Discussing proposal for a Directive, focussed on Articles 5, 9 and 19, and Annex 4. 22 pages. Some annotations concerning the changes made.
Received from European Council Archives 16/8/2021 – Folder 98 79	

st06725.en97 10-11/3/1997 Proceedings of working party on *in vitro* medical devices	Outcome of proceedings of Working Party on *in vitro* medical devices. Discussing proposal for a Directive, focussed on Articles 5, 7 and 9, and Annexes 2 and 4. 21 pages. Some annotations concerning the changes made. Methods of batch control are under discussion.
Received from European Council Archives 16/8/2021 – Folder 98 79	

st07546.en97 25/4/1997 Council draft Directive on *in vitro* medical devices	FULL DRAFT of proposed Directive on *in vitro* medical devices. 94 pages. Some annotations concerning the changes made.
Received from European Council Archives 16/8/2021 – Folder 98 79	

st07640.en97 29/4/1997 From the Council to the Permanent Representatives Committee	Amended proposal for a Directive on *in vitro* medical devices. 13 pages. Includes an introductory note on the process so far, and lists a number of outstanding issues. Has been agreed that tissue bank materials have to be rendered non-viable for any devices dealing with them in order for them to be covered by this Directive.
Received from European Council Archives 16/8/2021 – Folder 98 79	

st07794.en97 2/5/1997 Note for the Working Party from the French delegation	Note from French delegation on proposed Directive for *in vitro* medical devices. 5 pages. They are interested in strengthening medical device safety further. France has conducted a study, particularly in light of the BSE scandal, which is believed to have implications for this Directive. They want benefit/risk ratios to be applied to devices, particularly for those incorporating human tissue. They believe their proposal could have an effect on the whole sphere of medical device legislation.
Received from European Council Archives 16/8/2021 – Folder 98 79	

st08117.en97 14/5/1997 Note for the Working Party from the French delegation	Note from French delegation on proposed Directive for *in vitro* medical devices. 5 pages. France restates its dissatisfaction with the current draft, and argues that accepting it would require a diminishment of the regulatory standards which the country has already adopted.
Received from European Council Archives 16/8/2021 – Folder 98 79	

st08029.en97 15/5/1997 Note from the Presidency to the Council	Note from the Presidency to the Council, offering comments on the proposed Directive on *in vitro* medical devices. 13 pages. To avoid further delays, cells and tissues from humans could potentially be excluded from this Directive if no solution is forthcoming.
Received from European Council Archives 16/8/2021 – Folder 98 79	

st08029-co01.en97 16/5/1997 Note from the Presidency to the Council	Note from the Presidency to the Council, offering comments on the proposed Directive on *in vitro* medical devices. 3 pages. Presidency laying out options for potential ways forward.
Received from European Council Archives 16/8/2021 – Folder 98 79	

st08168.en97 19-20/6/1997 Proceedings of working party on *in vitro* medical devices	Outcome of proceedings of Working Party on *in vitro* medical devices. Discussing proposal for a Directive, focussed on Article 19 and Annex 1. 22 pages. Some annotations concerning the changes made.
Received from European Council Archives 16/8/2021 – Folder 98 79	

st09779.en97 4/7/1997 Proceedings of working party on *in vitro* medical devices	Outcome of proceedings of Working Party on *in vitro* medical devices. Discussing proposal for a Directive, focussed on Articles 1-4 and 19. 21 pages. Some annotations concerning the changes made.
Received from European Council Archives 16/8/2021 – Folder 98 79	

st10830.en97 10-11/9/1997 Proceedings of working party on *in vitro* medical devices	Outcome of proceedings of Working Party on *in vitro* medical devices. Discussing proposal for a Directive, focussed on Article 19 and Annex 1. 22 pages. Some annotations concerning the changes made.
Received from European Council Archives 16/8/2021 – Folder 98 79	

st10904.en97 26/9/1997 From the General Secretariat to the Permanent Representatives Committee	Report from the General Secretariat to the Permanent Representatives Committee, concerning the proposed new Directive on *in vitro* medical devices. 6 pages. Further discussion of whether to include human tissue in the Directive, and the outcome of efforts to reach an agreement. It has been decided to remove them from scope to ensure *in vitro* medical devices have legislation as soon as possible. Article 19 will be amended.
Received from European Council Archives 16/8/2021 – Folder 98 79	

st11479.en97 24/10/1997 From the Council to the Working Party on Economic Questions	FULL DRAFT of the proposed Directive on *in vitro* medical devices, sent from the General Secretariat of the Council to the Working Party on Economic Questions. 84 pages. Some annotations concerning the changes made.
Received from European Council Archives 16/8/2021 – Folder 98 79	

st11933.en97 5/11/1997 From the Council to the Working Party on Economic Questions	Drafts of Annexes 1, and 3-10, of the proposed Directive on *in vitro* medical devices, sent from the General Secretariat of the Council to the Working Party on Economic Questions. 44 pages. Some annotations concerning the changes made.
Received from European Council Archives 16/8/2021 – Folder 98 79	

st12072.en97 12/11/1997 Full draft of the Directive on *in vitro* medical devices	FULL DRAFT of the proposed Directive on *in vitro* medical devices. 78 pages. Some annotations concerning the changes made.
Received from European Council Archives 16/8/2021 – Folder 98 79	

st12192.en97 14/11/1997 Note from General Secretariat to Permanent Representatives Committee	Introductory note from General Secretariat to Permanent Representatives Committee concerning proposed Directive on *in vitro* medical devices. 8 pages. Provides an update on progress so far, and outstanding reservations.
Received from European Council Archives 16/8/2021 – Folder 98 79	

st12359.en97 14/11/1997 Note for the Working Party from the French delegation	Note from French delegation on proposed Directive for *in vitro* medical devices. 5 pages. Delegation want the procedure used to test reagents to be mandatory in nature. There are further elements which they also wish to be made mandatory.
Received from European Council Archives 16/8/2021 – Folder 98 79	

st12676.en97 24/11/1997 Note from General Secretariat to the Permanent Representatives Committee	Introductory note from General Secretariat to the Permanent Representatives Committee, concerning the proposed Directive on *in vitro* medical devices. 4 pages. The Working Party on Economic Counsellors met 21/11/1997 to discuss the proposals made by the French delegation.
Received from European Council Archives 16/8/2021 – Folder 98 79	

st12713.en97 25/11/1997 Note from General Secretariat to the Council	Introductory note from General Secretariat to the Council, concerning the proposed Directive on *in vitro* medical devices. 8 pages. Gives an account of the progress thus far, and the amendments to be made.
Received from European Council Archives 16/8/2021 – Folder 98 79	

st12416.en97 27/11/1997 Draft minutes of the 2051st Council Meeting (Internal Market)	Draft minutes of the 2051st Council Meeting (Internal Market). Proposal for a new Directive on *in vitro* medical devices has been submitted, and agreed to become an "A" item at a forthcoming Council meeting. 22 pages (only a couple relating to *in vitro* medical devices).
Received from European Council Archives 16/8/2021 – Folder 98 79	

st05255-ad01.en98 13/2/1998 Council's reasons for adopting the Directive on *in vitro* medical devices	Draft of the Council's reasons for adopting the Directive on *in vitro* medical devices. 10 pages.
Received from European Council Archives 16/8/2021 – Folder 98 79	

st05255.en98 6/3/1998 Copy of the Directive to be adopted on *in vitro* medical devices	FULL DRAFT of the Directive to be adopted on *in vitro* medical devices. 92 pages.
Received from European Council Archives 16/8/2021 – Folder 98 79	

st06907.en98 20/3/1998 List of "A" items for 2076th meeting of the Council	List of "A" items for 2076th meeting of the Council, including Directive on *in vitro* medical devices. 4 pages. Council meeting will take place 23/3/1998.
Received from European Council Archives 16/8/2021 – Folder 98 79	

st05255-re01ad01.en98 23/3/1998 Council's reasons for adopting the Directive on *in vitro* medical devices	Final version of the Council's reasons for adopting the Directive on *in vitro* medical devices. 12 pages.
Received from European Council Archives 16/8/2021 – Folder 98 79	

st07581.en98 21/4/1998 Proceedings of working party on *in vitro* medical devices	Outcome of proceedings of Working Party on *in vitro* medical devices. Discussing proposal for a Directive, focussed on devices incorporating human cells and tissues. 6 pages. Explanations of the positions adopted by different delegations. Discussion is somewhat directed around the reasons for thinking of an object as more like a device or a medicinal product.
Received from European Council Archives 16/8/2021 – Folder 98 79	

st09898.en98 13/5/1998 Proceedings of working party on *in vitro* medical devices	Outcome of proceedings of Working Party on *in vitro* medical devices. Discussing proposal for a Directive, focussed on French delegations suggestions for a further Directive on human cells and tissues. 4 pages.
Received from European Council Archives 16/8/2021 – Folder 98 79	

st09574.en98 18/6/1998 Note from General Secretariat	Note from General Secretariat concerning proposed Directive on *in vitro* medical devices. 6 pages. Concerning additions to the Common position, particularly 6 suggested amendments requested by Parliament.
Received from European Council Archives 16/8/2021 – Folder 98 79	

st10806.en98 17/7/1998 Proceedings of working party on *in vitro* medical devices	Outcome of proceedings of Working Party on *in vitro* medical devices. Discussing proposal for a Directive, focussed on Parliament's requested amendments, also a requested 'non paper' on human cells and tissues. 10 pages. Delegations state their positions on the amendment. With regard to human cells and tissues, blood might be incorporated into 93/42/EEC.
Received from European Council Archives 16/8/2021 – Folder 98 79	

st11331.en98 11/9/1998 Proceedings of working party on in vitro medical devices	Outcome of proceedings of Working Party on *in vitro* medical devices. Discussing proposal for a Directive, focussed on Parliament's requested amendments, also a requested 'non paper' on human cells and tissues. 8 pages. Delegations state their positions on the amendment. With regard to human cells and tissues, blood might be incorporated into 93/42/EEC. The delegations respond to this suggestion.
Received from European Council Archives 16/8/2021 – Folder 98 79	

st11410.en98 23/9/1998 General Secretariat notice on upcoming "A" items	General Secretariat notice on upcoming "A" items, including the Directive on *in vitro* medical devices. 2 pages. Move to have the Directive published.
Received from European Council Archives 16/8/2021 – Folder 98 79	

st03624.en98 25/9/1998 Full text of the Directive on *in vitro* medical devices	FULL TEXT of the Directive on *in vitro* medical devices. 92 pages.
Received from European Council Archives 16/8/2021 – Folder 98 79	

st11528.en98 2/10/1998 List of "A" items at 2120th Council meeting	List of "A" items at 2120th Council meeting, including Directive on *in vitro* medical devices. 4 pages. Meeting to be held 2/10/1998.
Received from European Council Archives 16/8/2021 – Folder 98 79	

st12051.en98 2/10/1998 Proceedings of working party on *in vitro* medical devices	Outcome of proceedings of Working Party on *in vitro* medical devices. Discussing proposal for a Directive, focussed on human blood products. 6 pages. Particularly interested in the mechanism for consultation between Member States, given the diversity of national requirements in this area.
Received from European Council Archives 16/8/2021 – Folder 98 79	

st11840.en98 8/10/1998 Note from Secretary-General of the Commission to the Council	Opinion of the Commission concerning the new Directive on *in vitro* diagnostic medical devices. 12 pages. Accepting the amendments suggested by the European Parliament.
Received from European Council Archives 16/8/2021 – Folder 98 79	