# MDPC Position Paper on EU General Data Protection Regulation

## I. Introduction

The Medical Device Privacy Consortium (MDPC) is a coalition of leading companies focused on health privacy issues in the medical device field. Members of the MDPC manufacture a diverse range of products, from molecular diagnostics to medical imaging equipment to implantable devices.

The MDPC welcomes the opportunity to provide comments on the current draft Regulation as it stands in the Parliament and the Council. The MDPC supports the Commission's efforts to reform the Data Protection Directive. In particular, the MDPC recognizes that harmonization of EU member state requirements can help to facilitate research into new and improved medical technologies. The MDPC also supports attempts to balance the privacy rights of data subjects while maintaining derogations that allow for data processing for the provision of care and other important public interests, including public health and medical research. These derogations are critical to medical technology innovation, quality assurance, and product support.

The MDPC's comments address three areas the Consortium feels are critical to being able to continue to provide healthcare professionals with the diagnostic, therapeutic, and preventive tools they need to deliver high-quality, life-saving medical care.

1. Derogations for medical device service technicians to provide patients and healthcare providers with device support, including monitoring system performance, upgrading software components, and fixing malfunctions.
2. Derogations for medical researchers to be able to access and analyze health data, so as to make improvements to existing devices and innovations into new technologies.
3. Provisions permitting cross-border access to data for processing and storage, recognizing the globalized nature of medical device research and support services.

## II. MDPC Positions

### 1. The MDPC supports derogations allowing health care professionals and others involved in the delivery of health care services to process personal data concerning health.

As proposed by the European Commission, Article 81(1) would allow health care professionals subject to an obligation of secrecy and other professionals subject to an equivalent obligation under Member State laws to process personal data concerning health for medical diagnosis and the provision of care or treatment. However, it should be recognized that health care professionals may be supported by numerous data processors who provide services ancillary to the delivery of patient care and who are bound by contract to maintain the confidentiality of the data.

Health care providers frequently utilize medical technology that requires ongoing or routine processing of personal data by third party service providers. The MDPC is concerned that such data processing is not clearly covered by the derogations in Article 81(1), potentially leading to interpretations that health care providers must obtain individualized consent from every patient for all support services. Modern health care relies on the use of increasingly complex medical technologies, and these technologies are typically supported by both in-house and external device technicians. If express patient consent were needed for these services, this would be an extreme administrative burden for health care providers (and impossible in emergency situations), and it would be impossible to practically implement. For example, if a hospital were to give each patient the choice of whether to allow his or her data to be processed by an MRI service technician, a single patient's choice to withhold consent would either need to be interpreted as overriding the consent provided by all other patients, or the non-consenting patient may not be able to receive appropriate diagnostic care in line with professional standards.

Following the Commission's proposal, the Parliament's text of Article 81(1)(a) permits the processing of personal data concerning health when necessary for "the purposes of preventative or occupational medicine, medical diagnosis, the provision of care or treatment, or the management of health care systems" but requires that the data is processed by "a health professional subject to the obligation of professional secrecy or another person also subject to an equivalent obligation of confidentiality under

Member State law or rules established by national competent bodies."[1] This text is not clear whether service providers supporting health care professionals and subject to confidentiality obligations imposed by contract are covered by the derogation. Further, although Article 81(1)(b) allows for processing without consent when necessary for "reasons of public interest in the area of public health, such as…ensuring high standards of quality and safety, inter alia for medicinal products or medical devices," it is not clear if routine patient care activities are covered by this derogation. The Council Presidency's 22 September proposed text of Articles 81(1)(a) and (b) are similar to the Parliament's text and suffer from the same interpretive problems.[2]

Clarification should be provided, whether through the addition of recital or operative language, to make clear that either or both derogations cover the full range of services that medical device support staff provide, including ongoing performance monitoring, troubleshooting, routine maintenance, upgrading of software, training, and device customization. For example, Article 81(1)(a) could be revised to make clear that persons subject to confidentiality obligations imposed by contract are also subject to the derogation. Alternatively, Recital 123 could be amended to make clear that the derogation in Article 81(1)(b) applies to medical device support services, regardless of whether the support provided pertains to only a single patient (e.g., consultation with a health care provider on the use of a device in a particular patient case) or to many patients (e.g., collection and analysis of safety events at an aggregate level).

**2. The MDPC supports a harmonized data protection framework for medical research.**

Analysis of data associated with the use of medical devices in clinical practice is vital for advancing our scientific understanding of diseases and conditions and the optimal use of medical devices to diagnose, prevent, and treat such diseases and conditions. "Real world" data can be important for comparing actual health outcomes to expectations based on clinical trials, identifying patterns in disease progression and the occurrence of acute events, and correlating adverse events to device usage, for example. The MDPC is concerned that Articles 81 and 83 may unduly limit the ability to effectively use data for medical research purposes, including for post-marketing surveillance studies in accordance with industry obligations or commitments.

The Parliament's text includes requirements in both Articles 81 and 83 for the processing of personal data concerning health for research purposes. Article 81(2) requires the consent of the data subject in order to process health data for research purposes. Article 81(2a) provides for the possibility of Member States to create exceptions to this consent requirement, but only with respect to research that serves "a high public interest" and where the research "cannot possibly be carried out otherwise." Even then, the data must be anonymised, or if that is not possible, "pseudonymised under the highest technical standards." The Parliament's text will, at best, lead to inconsistent requirements across Member States, making compliance difficult with respect to study of data from multiple Member States.

By contrast, Article 83d of the Council Presidency's 22 September proposed text allows personal data to be processed for "scientific purposes" provided that data enabling attribution to an identified or identifiable data subject is kept separately, where possible. Recital 126 clarifies that "scientific purposes" include "privately funded research carried out in the public interest." It is nevertheless unclear how the phrase "in the public interest" is to be interpreted; the MDPC therefore recommends adding thereafter: "such as medical research, including research into diagnostic, therapeutic, and preventive medical products." The MDPC is concerned that absent such a clarification, the language of the recital could lead to inconsistent interpretation across Member States.

**3. The MDPC supports allowing cross-border access to, and international transfer and storage of, appropriately protected personal data.**

The MDPC wishes to express general support for language allowing cross-border transfer and storage of personal data. The increasingly globalized nature of medical device research and support services makes it absolutely necessary to be able to transfer personal data across national borders. Device companies find it is frequently impractical or impossible to operate data storage and remote maintenance systems in every country in which a device is utilized. Further, research is often more effective on a large scale,

[1] European Parliament legislative resolution of 12 March 2014 on the Proposed Regulation (P7_TA(2014)0212).
[2] Council Document 13355/14.

encompassing many countries and regions of the world, and requiring transfer and storage from the countries of origin. The MDPC recognizes the sensitive nature of medical device-related data and the need for appropriate safeguards to protect confidentiality. As such, the MDPC supports language requiring reasonable security practices appropriate to the sensitivity and identifiability of the data rather than complete prohibitions on cross-border data transfers or mandated local storage.

## III. Conclusion

MDPC members rely on data-driven analysis and tools such as data analytics, m-health, and e-health to advance medical understanding and scientific progress. Information drives innovation. The proposed EU Data Protection Regulation should reflect a balance of individual data protection rights with recognition that the processing of personal data concerning health is necessary to advance medical technology innovation and deliver optimal health care.