Regulation of Medical Robots in Switzerland

The Example of Robotic Applications in Minimally Invasive Surgery

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Abstract: The use of robotic applications is a growing trend in Switzerland’s healthcare sector. For example, robots have been broadly in use in minimally invasive surgery. Robotic applications in minimally invasive surgery are an information-driven and safety-critical technology governed, amongst others, by data protection as well as medical device regulations. Doctors must make sure they understand how such robots process patient-specific information to comply with the relevant provisions of data protection regulations, which include, in the opinion of the authors, the requirement to seek informed patient consent. Robotic applications in minimally invasive surgery are (normally) medical devices under Swiss law. In this respect, the revised Therapeutic Product Act leads to a tightening of medical device regulations and an increase of the barriers to market entry for medical device manufacturers.

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I. Introduction

Robots are perceived as one of the most transformative technologies of the 21st century and have a huge societal and economic impact. Indeed, robots have already reached and transformed many industries: agriculture, manufacturing in the automobile industry, entertainment, rescue as well as home services. The use of robotic applications is also a growing trend in Switzerland’s healthcare sector. The variety of robotic applications used in healthcare today is remarkable. For example, robots have been broadly in use in minimally invasive surgery. Such robotic applications have the advantage to facilitate minimally invasive operations, to reduce blood loss and the length of time spent in hospital following a surgery, resulting in less pain and fewer post-operative com-


4 For more details and references see Klein Barbara/Gräf Birgit/Schömer Inga Franziska/Rosberg Holger/Rühricht Karin/Baumgarten Simon, Stiftung München (Hrsg.), Robotik in der Gesundheitswirtschaft - Einsatzfelder und Potenziale, Heidelberg 2018, 12 et seqq.
plications. Therefore, it does not surprise that experts predict an increase in small to medium-sized (surgical) procedures executed by autonomous robots in the future. In spite of these remarkable advantages, there are concerns pertaining to the use of robots in healthcare, in particular regarding minimally invasive surgery. These concerns include high financing costs of robotic applications, potential loss of data protection and patient security.

In the literature, robotic applications used in minimally invasive surgery are referred to either as “medical robots” or as “surgical robots.” In this article, we show that robotic applications in minimally invasive surgery are robots according to the so-called “sense-think-act paradigm” (cf. II.A). They are service robots (cf. II.B.), they are used in the healthcare sector and are a subgroup of the so-called medical robots (cf. II.C.).

This article aims at an analysis of the relevant data protection and medical device regulations applicable to the introduction and use of robotic applications in minimally invasive surgery. As far as can be seen, there are no articles in Switzerland analyzing the legal requirements for such medical robots. This is astonishing because robotic applications used in minimally invasive surgery have been on the market in Switzerland for years. For example, the “Kantons- spital St. Gallen” has been using such robots for almost 10 years. In the US, they have been used since the 1990s.

After having categorized robotic applications for minimally invasive surgery (cf. II.), we will analyze Swiss data protection and medical device regulations (cf. III.) and finish off with a conclusion (cf. IV.).

II. Categorization of Robotic Applications in Minimally Invasive Surgery

A. Robotic Applications in Minimally Invasive Surgery as Robots According to the “Sense-Think-Act Paradigm”

Any legal regulation relating to robots presupposes that we know what we mean by “robot”. But there is neither a consensus among roboticists how to define robots nor a legal definition for robots. According to the roboticists’ “sense-think-act paradigm” a robot is “a machine that senses, thinks, and acts. Thus, a robot must have sensors, processing ability that emulates some aspects of cognition, and actuators.”

Robotic applications used in minimally invasive surgery consist of an ergonomic input station (the so-called “operator”), which contains a 3D-monitor for visual reproduction and sensors for recording hand movements as well as several actuators (“teleoperators”), which carry the 3D-endoscope and several surgical instruments (executed by the surgeon). Therefore, robotic applications used in minimally invasive surgery fulfill the “sense-think-act paradigm” and are robots.

B. Robotic Applications in Minimally Invasive Surgery as Service Robots

Certain product safety regulations relate to sub-categories of robots, i.e. industrial robots and service robots. The “International Federation of Robotics” (IFR) divides robots into these two categories and bases its use of the term industrial robot on the definition of the “International Organization for Standardization” (ISO). This classification is valuable from a legal point of view because it can provide possible starting points for the legal analysis of robotic applications (e.g., in the area of the applicability of product safety regulations).

According to ISO 8373, an industrial robot is defined as “automatically controlled, reprogrammable multipurpose manipulator programmable in three or more axes”. In comparison to an industrial robot, a service robot is defined as “a robot that performs useful tasks for humans or equipment excluding industrial automation application. [...] The classification of a robot into industrial robot or service robot is done according to its intended application.”

Robots used in the healthcare sector in general and robotic applications in minimally invasive surgery in particular are normally seen as service robots because they “support the functioning of impaired indi-

6 KLEIN BARBARA ET AL., (Fr. 4), 160 et seq. Cf. further BECKER HEIDRUN et al., (Fr. 1), 179 et seq.; MAIER HELMUT (Fr. 2), 40.
7 GÖTHER JAN-PHILIPP, AJP 2017 (Fr. 3), 265.
8 CF. II.C.2 (Fr. 42).
11 BEEKEY GEORGE A., (Fr. 1), 17.
14 OBERMAIER TOBIAS, 267, 271 et seq.
iduals, rehabilitation of patients, care and medical intervention of patients”. In other words, robotic applications used in minimally invasive surgery have a support function. They are not being used to completely replace, but to assist medical staff (i.e., the surgeon). There is no need to worry about robots replacing humans on a big scale here.

In essence, the classification of robots into industrial robot or service robot depends on whether a robot is industrial. From a legal standpoint, we doubt that this binary distinction of robots is appropriate as a basis for product safety regulations, particularly due to the wide variety of robots. For example, a robotic application in minimally invasive surgery and a robot vacuum cleaner are both service robots, even though it is obvious that a medical robot requires other safety requirements than a robot vacuum cleaner. Thus, recent scholarship in law has sought to capture the wide range of robotic applications by using new criteria to classify robots, for example the structured environment of a robot (i.e., Locomat performs tasks in a structured environment) and its ability to learn and make decisions.

C. Robotic Applications in Minimally Invasive Surgery as a Form of Medical Robots Used in the Healthcare Sector

In this section, we show that medical robots are being used in the healthcare sector and that robotic applications in minimally invasive surgery are a subcategory of medical robots.

1. Medical Robots as a Category of Robotic Applications Used in the Healthcare Sector

Commercially, robotic applications have not fully succeeded in the healthcare sector yet. Nevertheless, their economic potential is huge. For example, according to ABB’s internal research, more than 60,000 non-surgical robots are expected to be working in hospitals by 2025. Therefore, it is not surprising that ABB, having already applied robotics and automation within the automotive, electronics, food as well as beverage and logistics industry, has recently opened a new global research hub for healthcare robotics in order to break into the non-surgical healthcare market.

There is no legal definition of what is meant by robotic applications used in the healthcare sector. However, in the absence of a legal definition, technical terms may be used differently by lawyers. This can lead to misunderstandings and confusions. Therefore, it may be helpful to refer to definitions from the robotics literature as a starting point for the legal analysis of robotic applications used in the healthcare sector.

Robotic applications used in the healthcare sector can be described as “the domain of systems able to perform coordinated mechatronic actions (force or movement exertions) on the basis of processing of information acquired through sensor technology, with the aim to support the functioning of impaired individuals, rehabilitation of patients, care and medical intervention of patients and also to support individuals in prevention programmes”. Thus, robotics for healthcare encompasses an impressively wide variety of robotic applications. Therefore, there are efforts in literature to categorize robotic applications used in the healthcare sector. For example, Maurits Buter et al. divide healthcare robots into the following categories: (1) Robot assisted preventive therapies and diagnosis (e.g., RP-7 by InTouch Technologies that is a medical mobile platform to treat patients remotely); (2) Robotic Assistive Technology (e.g., intelligent lower extremities prosthesis); (3) Robots supporting professional care (e.g., RIKEN to carry humans); (4) Robotics for rehabilitation treatment (e.g., Locomat by Hocoma to support the patient’s walking); (5) Robotics for medical interventions (e.g., robotic devices for minimally invasive surgery).

Based on this subdivision, two findings can be derived: First, robots for medical interventions form a separate category within the robotic applications used in the healthcare sector. However, we will use the terminology of medical robots instead, by which we mean robotic applications that belong to the 5th category according to the classification of Maurits Buter et al. Second, medical robots must be distinguished from “Personal Care Robots”. This second finding is relevant from a legal perspective. In

20 WILDHAEBER ISABELLE/LOHMANN MELINDA F., Robotertechnik – eine Einleitung, AJP 2017, 137 et seq.
21 WILDHAEBER ISABELLE/LOHMANN MELINDA F., AJP 2017 (Fn. 20), 137 et seq.
22 LOHMANN MELINDA F., Roboter als Wundheiler – eine zivilrechtliche Haftungsanalyse, AJP 2017, 152, 153 et seq.
23 WILDHAEBER ISABELLE/LOHMANN MELINDA F., AJP 2017 (Fn. 20), 137 et seq. Cf. also MAIER HELMUT (Fn. 2), 26, who proposes other criteria.
24 GUTHIER JAN-PHILIP, AJP 2017 (Fn. 3), 265.
27 ROBOTS BUSINESS REVIEW (Fn. 26).
28 Cf. BUTTER MAURITS ET AL. (Fn. 18), 12.
29 BUTTER MAURITS ET AL. (Fn. 18), 36 et seq. Cf. further KLEIN BARBARA ET AL. (Fn. 4), 12 et seqq.
30 Cf. for the definition of medical robots II.C.2.
contrast to certain robots supporting professional care or for rehabilitation treatment that qualify as “Personal Care Robots” (ISO 13482:2014), medical robots qualify as medical devices, which are subject to stricter regulation (cf. III.B). Finally, medical robots based on artificial intelligence must be distinguished from wholly software-based artificial intelligence which exerts no agency in the physical world. Therefore, such robots may be considered as hardware-based (embodied) artificial intelligence. In other words, purely software-based AI applications used in medicine are not robots (according to the “sense-think-act paradigm”). However, software-based artificial intelligence is also very important in modern medicine, e.g. to treat cancer.

2. Robotic Applications in Minimally Invasive Surgery as a Subcategory of Medical Robots

This section aims to clarify the question of whether robotic applications in minimally invasive surgery are a subcategory of medical robots. For this purpose, it is necessary to determine first what we understand by medical robots. The clarification of the term may provide guidance, for example, to determine the applicability of legal provisions in the area of the procedures for assessing conformity under medical device regulations.

There is no generally scientifically accepted definition of medical robots. However, the term “medical robot” refers to robotic applications that are intended to support the work of surgeons, for example by providing the necessary precision work in surgical procedures. Therefore, such robots are part of the so-called “computer-assisted surgery” or “computer aided surgery”. This term refers to surgical concepts and methods in which computer or robot technology is used to plan an operation. If medical robots are understood on the basis of this term, then robotic applications in minimally invasive surgery are to be regarded as a subcategory of medical robots. Medical robots are also being used in other surgical disciplines (e.g. neurosurgery, surgical orthopaedics, interventional and diagnostic radiology and microsurgery). For example, the “Da Vinci Surgical System” by Intuitive Surgical Inc. (USA) is one of the most successful robotic systems used in minimally invasive surgery, i.e. to remove the prostate because of prostate cancer (“radical prostatectomy”). Another robotic application (with semi-autonomous functions) in the field of robotic applications in minimally invasive surgery is the so-called “CyberKnife” by Accuray, which is in actual use for the treatment of brain cancer. These robots used for medical interventions are described in literature as medical robots or surgical robots.

In the following section, we will describe the data protection and medical device regulations for medical robots using the example of robotic applications in minimally invasive surgery. The findings of this legal analysis can basically be transferred to other types of medical robots.

III. Swiss Data Protection and Medical Device Regulations for Robotic Applications in Minimally Invasive Surgery

A. Swiss Data Protection Regulations

A robotic application in minimally surgery, such as the “Da Vinci Surgical System”, is an information-
1. Applicability of Data Protection Law

The applicability of data protection law is a complex issue. In Switzerland, data protection law in healthcare is based on a multi-level system that comprises the federal and cantonal regulations. The reason for this is that the Swiss Constitution (Cst.) does not give the Federation a comprehensive competence regarding data protection. As a consequence, the cantons have the right and obligation to regulate the data processing by cantonal and communal organs (cf. Art. 3 and Art. 42 Cst.). Therefore, as a general rule, data processing by cantonal and communal hospitals relating to robotic applications used in minimally invasive surgery is usually regulated by cantonal data protection legislation, whereas the Swiss Federal Act on Data Protection (FADP) is applicable as soon as personal data is being processed by such robots in private medical practices and private hospitals (cf. Art. 2 para. 1 lit. a FADP). However, there are some derogations from this aforementioned general rule. As a result, there might be difficulties distinguishing between the applicability of the FADP and the cantonal data protection legislation creating legal uncertainty. Materially, the cantonal data protection legislation is based on the FADP, mitigating the implications of the identified legal uncertainty. The data protection requirements for robotic applications in minimally invasive surgery are described in the next section using the example of the FADP.

2. Data Protection Requirements for Robotic Applications in Minimally Invasive Surgery

a) General Principles of Data Protection in the FADP

The FADP is applicable as soon as private parties or federal government process information about an identified or identifiable (natural or legal) person (cf. Art. 2 para. 1 lit. a and lit. b FADP and Art. 3 lit. a FADP). Whenever information about a patient is being collected or processed, the general principles of data protection must be (cumulatively) fulfilled, no matter whether the personal data is processed by a medical person or by a robotic application in minimally invasive surgery (cf. Art. 4, Art. 5 para. 1 as well as Art. 7 para. 1 FADP). Hence, the FADP is based on the principle of technology neutrality.

Information about a patient is data relating to health. Health data directly or indirectly provides information on the physical, mental or psychological state of health of a natural person. Such health data may have negative consequences for the persons concerned. Health data constitutes sensitive personal data in the

43 TAYLOR RUSSELL H./MENCIAZZI ARIANNA/FICHTELINGER GABOR/FIORINI PAOLO/DARIO PAOLO, 1657, 1658.
48 For more details and references see RÖTSCHE BERNHARD, Datenschutzrechtliche Aufsicht über Spatärzte. Zürich 2012, 41 et seqq.
sense of Art. 3 lit. c no. 2 FADP. The FADP provides for higher requirements for the processing of health data in some cases.\(^{55}\)

As Florent Trouvenin demonstrated, the general data protection principles of data processing originate from the field of public law.\(^{56}\) Therefore, some of these general principles of data protection (e.g., the principle of proportionality stipulated in Art. 4 para. 2 FADP) may not have the same meaning if private parties process personal data in the direct interest of the data subject.\(^{57}\) This insight is important in the context of robotic applications used in minimally invasive surgery, as personal data is usually collected in the interest of patients (and not for purely economic purposes). In our opinion, the applicability of the general principles of data protection (in particular with regard to the principle of purpose limitation according to Art. 4 para. 3 FADP as well as the principle of proportionality according to Art. 4 para. 2 FADP) should therefore be less strict, as long as personal data is being processed by robotic applications in the interest of the patient.

b) Big Data-Based Robots and the Principles of Purpose Limitation and of Proportionality

Robotics applications can use "Big Data" analytics tools.\(^{58}\) "Big Data" can be understood as a process consisting of collecting, integrating, interpreting data and using interpretation results.\(^{59}\) The comparison of the patient’s data with data from other patients is characteristic for "Big Data" in the medical context.\(^{60}\) It is not simple to find out if a robotic application used in minimally invasive surgery is based on Big Data. A robot based on Big Data may run the risk of breaching the principle of purpose limitation (cf. Art. 4 para. 3 FADP).\(^{61}\) Therefore, medical persons need to make sure they know (with the support of IT specialists) how a robotic application processes patient-specific information. For example, if a patient’s data is linked to data from other patients for scientific purposes, the patient’s data may be processed for other purposes than the one it was originally collected for. Furthermore, robotic applications in minimally invasive surgery based on Big Data may also infringe the principle of proportionality according to Art. 4 para. 2 FADP, since these robots will process more than the personal data required to treat the patient.\(^{62}\)

Whenever robotic applications in minimally invasive surgery process patient’s data contrary to the general principles of data protection, this data processing constitutes an unlawful breach of privacy unless it is justified by the consent of the injured party or by an overriding private or public interest or by law (cf. Art. 12 para. 2 lit. a in conjunction with Art. 13 para. 1 FADP). Therefore, we recommend the medical person to seek consent from the patient before collecting and processing their personal data by a robotic application in minimally invasive surgery working with Big Data. As shown, information about a patient is data relating to health (cf. Art. 3 lit. c no. 2 FADP). As a result, the consent has to be given voluntarily on the provision of adequate information as well as expressly (cf. Art. 4 para. 5 FADP).

c) Cloud- and Network-Based Robots in the Field of Tension to Art. 10a and Art. 6 FADP

Robotics applications in minimally invasive surgery may also be connected to a cloud via a network such as the Internet or Intranet for data transmission and processing depending on the type of robot. It is a complex issue to understand the data transmission and processing of a cloud- and network-based robot without the support of IT specialists, particularly when it comes to the question of what people have access to personal data. The processing of data relating to health by (foreign) third parties via cloud- and network-based robots may be in contradiction with data processing by third parties (cf. Art. 10a FADP), cross-border disclosure (cf. Art. 6 FADP) as well as to violation of professional secrecy (cf. Art. 321 of the Swiss Criminal Code\(^{63}\)), because unauthorized third parties may have access to the information about the relevant patient.\(^{64}\) As a result, we advise to process

\(^{55}\) Cf. for example III. A. 2 b).


\(^{58}\) Cf. Taylor Russell H./Mencassi Arianna/Fichtinger Gabriele/Fiorini Paolo/Dario Paolo, 1657, 1658.


\(^{62}\) Cf. Aebi-Möller Regina E./Fellmann Walter/Gächter Thomas/Rütsche Bernhard/Tag Briegleit (Fn. 49, 439.


\(^{64}\) Swiss Criminal Code of 21 December 1937 (SR 311.0).

\(^{65}\) Cf. Wohlers Wolfgang, Auslagerung einer Datenbearbeitung und Berufsgeheimnis (Art. 321 StGB), Zürich 2016, 6 et seqq.
personal data with the help of a robot connected to a network solely with the patient's consent (cf. Art. 321 no. 2 of the Swiss Criminal Code).

B. Swiss Medical Device Regulations

Robotic applications, such as the "Da Vinci Surgical System", are safety-critical systems⁶⁶; they may injure patients or medical staff by performing medical tasks. For this reason, it is crucial to have an effective regulation with provisions averting dangers arising from such robots. In Switzerland, the product safety regulation of medical devices is essentially based on the Federal Act on Medicinal Products and Medical Devices (TPA)⁶⁷ and the Medical Devices Ordinance (MedDO)⁶⁸, amongst others. Therefore, it must be first clarified whether robotic applications used in minimally invasive surgery are medical devices in the sense of the TPA (and MedDO). Second, we present the medical device legal requirements for robotic applications used in minimally invasive surgery which are regarded as medical devices in the sense of the TPA.

Legal developments in medical device regulations have been quite dynamic in recent times. The National Council and the Council of States adopted unanimously the partial revision of the TPA on 22 March 2019 and it should enter into force in the first half of 2020.⁶⁹

1. Robotic Applications in Minimally Invasive Surgery as Medical Devices?

The TPA is only applicable to a robotic application in minimally invasive surgery if it is a medical device. Medical devices are defined as "products [...] which are intended to have, or are presented as having, a medical use and whose principal effect is not obtained with a medicinal product" (cf. Art. 4 para. 1 lit. b rev.TPA). Therefore, a robotic application in minimally invasive surgery is a medical device in Swiss law if its use is medical and its action is not obtained with a medicinal product. For example, the "Da Vinci Surgical System" performs medical tasks such as the removal of the prostate (e.g., in the case of prostate cancer), which qualifies as medical use. It may be difficult, in practice, to distinguish between robots with and without medical use,⁷⁰ especially because the legal term "medical use" in the sense of the TPA is based on the concept of a disease which is not a genuinely legal concept. In contrast to medicinal products, medical devices achieve their intended principal medical effect mainly not by pharmacological, immunological or metabolic means, but by mechanical, physical or physicochemical means.⁷¹ In this respect, the "Da Vinci Surgical System" is not a medicinal product because it achieves its medical effect by mechanical means. The "Da Vinci Surgical System" used in minimally invasive surgery is a medical device because it is clearly based on medical use and it is not a medicinal product (cf. Art. 4 para. 1 lit. b rev.TPA). As a result, the TPA and MedDO are applicable to the "Da Vinci Surgical System".

2. New Obligations for the Manufacturers of Robotic Applications Used in Minimally Invasive Surgery

The revised TPA leads to a tightening of medical device regulations and an increase of the barriers to market entry for medical device manufacturers.⁷² Thus, the "rev.TPA" provides, e.g., a duty to register robotic applications used in minimally invasive surgery and to identify them (cf. Art. 47 rev.TPA). Manufacturers must now assign a unique product identification ("UDI") to the robotic application used in minimally invasive surgery and register such a ("rev.TPA") robot in an information system to be set up (cf. Art. 62c rev.TPA) or in the European database for medical devices ("Eudamed"). Furthermore, the "rev.TPA" stipulates a duty for manufacturers of robotic applications used in minimally invasive surgery to prepare technical documentation (cf. Art. 47a rev.TPA) and a duty to introduce and maintain a quality management system (cf. Art. 47b rev.TPA).⁷³ The entry into force of the MedDO is also planned for the first half of 2020.⁷⁴ The draft consultation of the MedDO contains the obligation for manufacturers to employ at least one person in their organisation who has the necessary expertise in the field of medical devices and is responsible for compliance with the relevant regulatory requirements.⁷⁵

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⁶⁷ Federal Act on Medicinal Products and Medical Devices of 15 December 2000 (Therapeutic Products Act, TPA, SR 812.21).
⁶⁸ Medical Devices Ordinance of 17 October 2001 (MedDO, SR 812.213).
⁷⁰ Wildhaber Isabelle / Lohmann Melinda F., AJP 2017 (Fn. 20), 138 et seq. with regard to ISO 13485:2016.
⁷² Kesselerling Felix / Reutz-Demont Janine, Eckpunkte der neuen Medizinprodukte-Regulierung, LSR 2019, 383, 191
⁷³ Cf. Kesselerling Felix / Reutz-Demont Janine, LSR 2019 (Fn. 72), 185 et seq.
⁷⁵ Bundesamt für Gesundheit (Fn. 74), 30 et seq.
3. Placing on the Market of Robotic Applications Used in Minimally Invasive Surgery

The TPA regulates different legal aspects regarding placing on the market, distribution and monitoring of a medical device. Medical devices do not require an official authorization in contrast to medicinal products; instead they must get a certification. The conformity assessment by the legal manufacturer and market surveillance by Swissmedic replace an official approval in order to guarantee the safety and efficacy of medical devices in Switzerland. Medical devices are divided into different classes (I, IIa, IIb und III) for this conformity assessment. In view of the high level of detail of the classification rules and their adaptation to the concrete purpose of the respective product, the classification of a robotic application used in minimally invasive surgery must be determined in the concrete individual case and cannot be determined in general. To get certified, the manufacturer of a robotic application used in minimally invasive surgery must prove that this robot is in line with the essential legal requirements (cf. Art. 45 para. 2 TPA). These essential legal requirements do not include detailed technical rules. It is difficult for the manufacturer of robotic applications in minimally invasive surgery to know whether their product complies, as these essential legal requirements are too vague and too open. Therefore, technical standards of private standardization bodies substantiate these essential requirements. For example, EN ISO 13485:2016 (“Medical devices – Quality management systems – Requirements for regulatory purposes”) as well as DIN EN 80601-2-78:2018 (“Medical Electrical Equipment – Part 2–78: Particular requirements for the basic safety and essential performance of medical robots for rehabilitation, assessment, compensation or alleviation”) (available as a draft) are two technical standards which stipulate safety requirements for robotic applications in minimally invasive surgery. However, as these standards are only “soft law”, the manufacturer of a robotic application in minimally invasive surgery is not legally obliged to fulfill these technical standards. Compliance by manufacturers with the (designated) technical standards gives rise to the rebuttable presumption that a robotic application used in minimally invasive surgery meet the essential safety and performance requirements.

4. Product Monitoring of Robotic Applications in Minimally Invasive Surgery

Product monitoring after placing a robotic application in minimally invasive surgery on the market is an essential part of the medical devices regulation concept. The manufacturer of a robotic application in minimally invasive surgery must introduce and maintain a product tracking system (“post-market surveillance system”). The manufacturer must actively and systematically collect, record and analyse data on the quality, performance and safety of the robotic applications in minimally invasive surgery throughout its lifetime in order to identify and take any measures necessary to avert danger or improve the robot. It is unclear if the manufacturer of a robotic application in minimally invasive surgery must carry out an on-the-spot inspection. If there is a concrete suspicion of endangering a person’s health, the manufacturer must carry out an on-the-spot inspection. In our opinion, an effective product tracking system requires a close collaboration between the manufacturer and the users of a robotic application used in minimally invasive surgery by sharing product-specific information in order to reduce potential health risks.

IV. Conclusion

Robotic applications in minimally invasive surgery such as the “Da Vinci Surgical System” are an information-driven and safety-critical technology. There-
fore, data protection law as well as medical device regulations govern this robot type, such as the “Da Vinci Surgical System”. Whenever such robots collect and process information of a patient based on Big Data, we recommend the doctor to seek consent from the patient. The same goes for robotic applications used in minimally invasive surgery connected to a cloud via a network. Doctors must make sure they understand (with the support of IT specialists) how these robots process patient-specific information to comply with the relevant provisions of data protection law. Robotic applications in minimally invasive surgery, such as the “Da Vinci Surgical System”, are (normally) medical devices under Swiss law. As a result, the provisions of the TPA and MedDO are applicable. Manufacturers of robotic applications in minimally invasive surgery must introduce and maintain a product tracking system. An effective product tracking system requires a close collaboration between the manufacturer and users of the “Da Vinci Surgical System” in order to reduce potential health risks.