

## Quality Manual

### Quality Policy

We are committed to comply with the requirements of an accredited certification body, the MDR Medical Device Regulations 2017/745, the Malaysian Medical Device Act 2012, Act 737, the Malaysian Medical Device Regulations, the requirements for participating EU Notified Body Partner under the TCP Technical Cooperation Program (Taiwan), and the requirements for recognition as MDSAP Auditing Organizations.

#### We ensure:

- Complying with applicable standards and regulations
- Establishing up-to-date and efficient QM procedures
- Improving our services and performance
- Serving our customers with a high degree of professionalism and responsiveness
- Deliver in accordance with stakeholders' expectations
- Maintaining our independence and impartiality by the Committee for Safeguarding Impartiality

We are committed to realize following:

#### 1. Our accreditation/designation/recognition is our most valuable goods, so

- We will never use our accreditation, designation or recognition in a manner that brings the accreditation body or designating or recognizing body into disrepute.
- We make claims only with respect to our accreditation, designation and recognition.
- We will never make a statement regarding accreditation, designation or recognition that may be considered misleading or unauthorized.
- We use the accreditation, designation and recognition marks only for premises that are included in our scope.
- We ensure that our advertising or promotional activities in no way imply or are capable of leading to an inference that our service will offer customers earlier market access or be quicker, easier or less stringent than that of other certification or notified bodies.
- We ensure that our activities are offered without any commercial or financial pressure and exclude any bias in the certification or conformity assessment activities.
- We will never certify the quality management system of another certification or notified body, offer or provide consultancy to our certified customers.
- Consultant companies are not permitted to market or link their activities to our certification activities. We will act if we see inappropriate claims from consulting companies stating or implying that certification/conformity assessment would be simpler, easier, faster or less expensive if customers are using their services. Vice versa, we will not state or imply that certification/conformity assessment would be simpler, easier, faster or less expensive if a specific consultancy organization were used.

#### 2. Our focus is customer compliance

- Our service is available to all interested parties anywhere in the world.
- All customers are treated equally regardless of nationality, organization, company or individual.
- We get the requirements of our customers, review them, and meet them within the scope of the regulations and requirements.
- We built up trust placed in us by health professionals, patients, authorities, and the medical devices industry through neutrality, competence and professionalism of our services
- We enable the appropriate allocation of a continuous and high-quality service.
- We remain fully responsible, even if we are using subcontractors for specific tasks.
- We operate in accordance with a set of consistent, fair and reasonable terms and conditions, taking into account the interest of small and medium-sized enterprises as defined in Recommendation 2003/361/EC in relation to fees.
- We ensure impartiality, independent decisions and a fair and correct relationship to every customer.

### 3. Our employees and subcontractors are the cornerstone of our reputation and success

- Our Top Management undertakes all steps needed and provides the necessary means to achieve the employment of a sufficient number of qualified staff members to be able to perform our services.
- We ensure the qualification and development of our personnel by offering trainings, exchange of experiences and product specific events.
- Our independency, impartiality and objectivity of our internal and external personnel are prerequisites for our acting
- Our Personnel is committed to the DNV and Team NB Code of Conduct.
- We maintain our neutrality and exclude conflict of interest by effective self-obligation and regular control of:
  - No activities as consultant for medical device companies, designer, manufacturer, supplier, installer, purchaser, seller, marketer, owner or maintainer of the devices we assess, nor the representative of any of those parties for at a minimum the last three years.
  - No financial advantage of our assessors, reviewers and decision makers depending on the results of assessments.
  - No intimidation and self-interested threats between customer and our personnel.
  - Disclosure of any circumstances that may present for us a conflict of interest.
- We will act and respond to any threats to our impartiality arising from actions of other persons, bodies or organizations

### 4. Confidentiality is of priority

- All documents, information, product samples, and any other objects submitted to us by our customers shall be treated as "strictly confidential" in all cases and by all staff members. All individuals, groups including subcontractors and companies involved in any certification or conformity assessment process are obliged by contract to maintain strict confidentiality.
- All our personnel as well as all our subcontractors protect proprietary rights.
- All our personnel as well as all our subcontractors observe professional secrecy in carrying out their tasks, except to our national authorities or any competent authority for medical devices in the EU or the Commission, or the MDSAP participating Regulatory Authorities.

DNV MEDCERT ensures that our quality policy and the Code of Conduct (530101) is understood, implemented and maintained at all levels of our organization, including our subcontractors and our subsidiaries.

DNV MEDCERT keeps signed statements of adherence to the Code of Conduct for all personnel and subcontractors involved in regulatory audits. For persons involved in MDSAP audits, the statement is renewed annually.