RESELLER QUALITY ASSURANCE CONDITIONS (RQAC)

COLTENE Group (includes all companies of the COLTENE Group), www.coltene.com

1. Objective

This RQAC outlines the responsibilities of COLTENE and the RESELLER with respect to the quality assurance of the current PRODUCT portfolio of COLTENE including PRODUCTS with COLTENE as manufacturer as well as present and future PRODUCTS delivered to the RESELLER by COLTENE, as manufacturer, authorised representative, importer or distributor under the Regulation EU 2017/745 (MDR), 93/42 / EEC (MDD) and MDSAP, in order to ensure regulatory compliance and safety and performance of the PRODUCT portfolio of COLTENE (hereinafter "PRODUCTS" or "PRODUCT"), in specific but not limited with respect to following topics:

- Definition of tasks and responsibilities of both the RESELLER and COLTENE with regard to monitoring and reporting of quality defects, feedbacks and complaints regarding the PRODUCTS
- Definition of tasks and responsibilities concerning storage as well as transportation conditions
- Definition of tasks and responsibilities concerning the creating and keeping of seamless batch tracking records
- Definition of tasks and responsibilities with regard to post market surveillance

Both parties have defined a contact person each. Alternatively, the exchange of information shall take place via the companies main address.

2. Scope

This document constitutes a Quality Agreement only and is not intended to represent a Reseller Agreement or to describe financial terms or production or distribution volumes. The RQAC does not represent or replace any other agreement and/or amendment(s) thereto between COLTENE and RESELLER.

3. Obligations of the RESELLER

3.1 RESELLER will support COLTENE in all reasonable ways in order to fulfill regional regulatory requirements in countries where RESELLER will sell PRODUCTS. In this context, RESELLER will monitor regional regulatory requirements and will immediately inform COLTENE in case regional regulatory requirements will change and may affect PRODUCTS or obligations of COLTENE or RESELLER.

3.2 RESELLER will allow COLTENE, the notified body of COLTENE and the responsible authorities to audit or inspect RESELLER's facility and Quality Management System (QMS). For audits, registration or an appointment should be made at least 30 working days in advance.

3.3 RESELLER is aware of his regulatory obligation to verify that the following requirements are met before making a PRODUCT available on the market:

(a) RESELLER needs to make sure that the PRODUCTS comply with the country specific regulatory requirements:

- This includes the responsibility that COLTENE receives all language and identification information, as well as the participation in the creation and corrections.
- Registrations are only carried out by COLTENE. If this is not possible due to country-specific regulations and law, the rights to register and use the registrations are agreed separately for the RESELLER.
- Existing approvals will be returned to COLTENE upon request.

RESELLER shall obliged to report all registration processes to COLTENE and to send corresponding copies to COLTENE without being asked.

(b) The PRODUCT is accompanied by the information to be supplied by the manufacturer according appropriate regulatory requirements (e. g. as set out in MDR);

(c) for imported devices, the importer has complied with the appropriate regulatory requirements (e. g. as set out in MDR) and the appropriate language verion for its market;

In order to meet the requirements referred to in points (a), (b) and (c) of the first subparagraph the RESELLER may apply a sampling method that is representative of PRODUCTS supplied by the RESELLER. Where RESELLER considers or has reason to believe that a PRODUCT is not in conformity with the applicable regulatory requirements, it shall not make the PRODUCT available on the market until it has been brought into conformity by COLTENE, and shall inform COLTENE immediately. RESELLER is prohibited from owning any rights to the product without the approval of COLTENE.

3.4 If RESELLER considers or has reason to believe that a device which they have made available on the market has a quality defect or is not in compliance with regulatory requirements, it is also legally permissible to inform COLTENE first, otherwise the reporting sequence according to national laws must be observed. If there is any suspicion, COLTENE shall be informed immediately. RESELLER shall co-operate with COLTENE and with competent authorities to ensure that the necessary corrective action to bring that device into conformity, to withdraw or to recall it, as appropriate, is taken. Where RESELLER considers or has reason to believe that a PRODUCT presents a serious risk, it shall also immediately inform the competent authorities of the member states in which it made the device available, giving details, in particular, of the non-compliance and of any corrective action taken. In case of a recall of PRODUCTS, RESELLER shall promptly forward requisite information to the final users or further distributors.

3.5 If RESELLER has received complaints or reports from healthcare professionals, patients or users about suspected incidents related to a PRODUCT they have made available, RESELLER forward this information to COLTENE within 2 working days after notice. RESELLER shall keep an up-to-date register of complaints, of non-conforming devices and of recalls and withdrawals, and keep COLTENE closely informed of such monitoring and provide them with any information upon their request.

3.6 RESELLER shall, upon request by a competent authority, provide it with all the information and documentation that is at their disposal and is necessary to demonstrate the conformity of a device.

RESELLER shall be considered to have fulfilled the obligation referred to in the first subparagraph of 3.6 when COLTENE provides the required information. RESELLER shall cooperate with competent authorities, at their request, on any action taken to eliminate the risks posed by PRODUCT which they have made available on the market. RESELLER, upon request by a competent authority, shall provide free samples of PRODUCT or, where that is impracticable, grant access to PRODUCT.

3.7 RESELLER shall maintain full records of all sales activities (e. g. batch tracking, sales addresses, UDIs, shelf life, lot or serialnumber) for the lifetime of a PRODUCT plus 2 years, but not less than 15 years.

3.8 RESELLER undertakes to own and maintain its own database of quality defects and complaints, including incidents. The data shall enable seamless batch tracking. Upon request, the RESELLER must provide information of the database, which concerns COLTENE PRODUCTS to COLTENE in a computer readable format.

3.9 RESELLER will collect relevant post market surveillance data and will support COLTENE upon request undertake to carry out periodic reviews to analyse the relevant post market surveillance data within periodic post market surveillance (refer to 4.4). RESELLER will also review records of service activities to analyze if the information captured during the service activity should be handled as a complaint or may serve as an input to COLTENE's improvement process.

3.10 RESELLER shall ensure that, while the device is under their responsibility, storage or transport conditions comply with the conditions set by COLTENE. For unambiguous definition of storage and transport conditions for a PRODUCT, RESELLER may set up individual storage and transport instruction and/or contract. Further, RESELLER shall not modify the presentation of PRODUCTS in any way (contents, labelling, user manual, products, etc.) and it shall not sell to final user any PRODUCTS of which the expiration date has passed.

3.11 RESELLER may create own advertising material in style and color but never may change the main product information incorporated in the Master Documentation received by COLTENE. Any information of the approved documents concerning the use, safety, combination and maintenance is to be taken over in complete original terms. At the request of COLTENE, the RESELLER is also obliged to withdraw marketing material from the market. Trademarks may only be used with the consent of COLTENE. In addition the distributor has to adhere to local laws and regulations.

3.12 RESELLER takes the full responsibility for the distribution records and their retention. The distribution records shall enable seamless batch tracking and the RESELLER shall retain the distribution record in respect of the medical device for the longer of

(a) the projected lifetime of the PRODUCT (i. e. shelf-life), and

(b) 10 years, or in case of implantable devices 15 years after the date PRODUCT is shipped.

3.13 In regions where UDI (Unique Device Identifier) is enforced, RESELLER shall record UDI on the service records. RESELLER will retain the following records for a period of 10 years (Australia, Brazil, Canada and US), or 15 years (Japan):

a) Users training records for both technicians and operators (where applicable), 5 years in Australia and Japan.

b) Medical device distribution records (2 years in Canada)

c) Service records

d) Records of equipment installation (and testing where applicable)

e) Records of device decommissioning (where applicable).

3.14 RESELLER ensures furthermore that his local distribution partners comply with the above mentioned requirements as outlined in 3.7 - 3.13. and concludes a RQAC analogue written contract with them. RESELLER ensures that PRODUCTS with a CE approval according to 93/42 / EEC (MDD) may only be sold until May 24th, 2025.

3.15 RESELLER shall have documented procedures in place in respect to

- Document Control
- Record Control
- Complaint Handling
- Management of Nonconformities
- Identification and Traceability
- Vigilance and Recall
- Post Market Surveillance and corrective and preventive action
- Personnel Training
- Storage

3.16 If a territory is defined in a RESELLER contract with COLTENE, RESELLER shall not put on the market the PRODUCTS outside the territory defined with COLTENE.

4. Obligations of COLTENE

4.1 COLTENE will support RESELLER in any reasonable way. COLTENE commits to fulfill the country specific requirements and will provide relevant documentation to RESELLER in order to help it to fulfill its obligations as listed in chapter 3.

4.2 COLTENE undertakes to notify the RESELLER promptly in writing of all quality defects of PRODUCTS which become known to it that has a potential impact on the RESELLER'S existing and/or future stocks.

4.3 COLTENE undertakes, where relevant, to notify the RESELLER promptly of all incidents which become known to it outside the RESELLER'S territory. Once completed and upon request, COLTENE will furnish the RESELLER with a complete report of the investigation into the incident so that the RESELLER can fulfil its local regulatory responsibilities, where relevant.

4.4 COLTENE and the RESELLER undertake to carry out periodic reviews to analyse the relevant post market surveillance (refer to 3.9).

4.5 COLTENE has to notify the RESELLER in case changes on a PRODUCT design/specifications are planned which may have impacts on the RESELLER's existing and/or future stocks.

4.6 COLTENE will fulfill its obligations as manufacturer, authorised representative, importer or distributor as set out in corresponding regulation.

4.7 COLTENE provides various forms (e. g. complaint, vigilance, PMS, …) and communicates reporting channels that must be complied with.

5. Duration of Validity

This RQAC is valid for all transactions between COLTENE and RESELLER, all imports/sales of PRODUCTS respectively during the shelf life time of every sold PRODUCT. Thereafter, the RESELLER must still archive all necessary documents and records that the RESELLER is required to draft and update as stated herein, as well as those documents that are part of its quality management system, for a period of at least 15 years. These documents must be provided to COLTENE upon its request. In particular, this includes but is not limited to the following:

- Complaint Handling
- Identification and Traceability
- Vigilance and Post Market Surveillance
- Post Market Clinical Follow UP (PMCF)

6. Place of Performance and Place of Jurisdiction

The place of performance for all deliveries governed by the contractual relationship between COLTENE and the customer shall be the place of shipping (as defined in the corresponding order confirmation). The place of jurisdiction shall be the business domicile of the relevant COLTENE company concluding the sale with the RESELLER. However, COLTENE reserves the right to sue the customer for claims or debts due at the place of jurisdiction of the customer's registered office or residence.

7. Invalidity, Amendment to these RQAC

Should any individual provisions of the RQAC be or become invalid in whole or in part, this shall not affect the validity of the remaining provisions. The invalid provision shall be replaced by a valid provision or stipulation that approximates as closely as possible to the meaning and purpose of the invalid provision.

COLTENE reserves the right to amend the RQAC at any time without giving reasons or prior notice. The version valid at the date of order shall apply in each case. Otherwise, any deviations from the RQAC shall be valid only if expressly agreed to by COLTENE and set down in writing.

8. Applicable Law

The contractual relations between the customer and COLTENE shall be governed exclusively by the RQAC and, subsidiarily, by the provisions of Swiss Law. The validity of the provisions of the United Nations Convention on Contracts for the International Sale of Goods is hereby expressly excluded.

Approved: Altstätten, December 1, 2020

COLTENE

006278 12.20