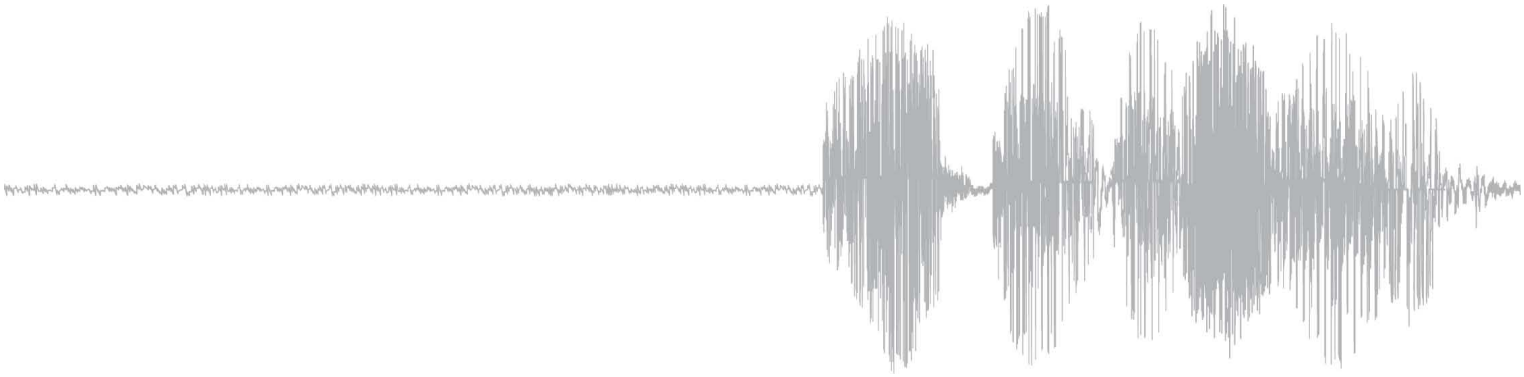

Quality Terms and Conditions

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Approver: Walter D'Avolio (wdavolio)
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Hear now. And always

Cochlear®

QUALITY TERMS AND CONDITIONS

To ensure that Cochlear's products and services satisfy relevant quality and regulatory requirements, Cochlear requires the Supplier to ensure that all Products or Services which relate to Cochlear's manufacturing and/or R&D activities are produced and delivered in accordance with the terms and conditions of this document. This document is intended to supplement any commercial terms signed or agreed between the Parties to govern the supply of Products or Services to Cochlear.

1. Scope of Products or Services covered by these Quality Terms and Conditions

Unless otherwise agreed in writing by the Parties, these Quality Terms and Conditions ("Agreement") apply to Products supplied and Services provided by the Supplier to Cochlear (or to third party manufacturers or suppliers nominated by Cochlear) relating to Cochlear's manufacturing and/or R&D activities.

2. Order of precedence

Unless otherwise agreed in writing by the Parties, if a conflict arises between the requirements of this Agreement and other Cochlear documents applicable to the Supplier, the following order of precedence shall apply to the extent of such conflict:

a) this Agreement;

b) Purchasing or supply agreements;

c) Specifications, Statement of Works documents and any referenced engineering and technical documentation.

This Agreement shall not apply if a Supplier Quality Agreement, Lite Supplier Quality Agreement or equivalent has been agreed in writing between the Parties.

3. Assignment

Neither Party may assign any or all of its rights or obligations under this Agreement without the other Party's prior written consent, which will not be unreasonably withheld, unless the assignment is to an Affiliate of the Party in which case either Party may assign any or all of its rights or obligations under this Agreement by providing the other Party with ninety (90) days prior written notice.

4. Audits

4.1 Cochlear audits of Supplier facilities

The Supplier will allow Cochlear, its authorised representatives and any regulator, notified body, certifying body or competent authority to perform audits of its sites. The audits may cover any systems, documentation and other requirements related to the Products or Services provided by the Supplier to Cochlear and will be conducted at mutually agreed dates and times, with the exception of unannounced audits by any regulator, notified body, certifying body or competent authority.

4.2 Auditing of Third Party Suppliers

The Supplier must use best endeavours to ensure that in each of its agreements with any third party suppliers, that Cochlear, its authorised representatives and any regulator, notified body, certifying body or competent authority, has a right to perform audits of the third party supplier's facilities, systems, documentation, and other requirements related to this Agreement, as and when required by Cochlear.

5. Change control and deviations

The Supplier must maintain a documented change control process to manage permanent or temporary changes (deviations) and notify Cochlear as soon as practicable of any proposed changes that may affect the form, fit or function of Products and/or Services delivered to Cochlear. This includes manufacturing process changes and changes undertaken by Third Party Suppliers. Cochlear may require review and approval of changes that have the potential to affect the safety, performance and effectiveness of Cochlear's Products.

6. Data Storage / Record Keeping

The Supplier shall maintain records of the traceability and test results for a period of 10 years in a secure location, unless otherwise notified by Cochlear. After this retention period, the Supplier shall notify Cochlear of any intent to dispose of such records and provide reasonable opportunity for Cochlear to collect relevant traceability and test data from the records.

7. Material traceability

The Supplier must maintain records which allow traceability from the delivered Product batch or Service back to the initial lot of all raw materials, components, sub-assemblies or servicing records. The records shall include the results of all applicable test, inspection or other acceptance activities and must identify all key procedures and processes used in the manufacture of Products or performance of Services.

8. Minimum Security Standards

If the Supplier is supplying a Product to Cochlear which is networkable or programmable, the requirements as set out in this clause 8 must be adhered to.

8.1. Policy Control

The Supplier shall maintain a documented information security policy that is consistent with best industry practice. The Supplier shall ensure its information security policy and any appropriate training is provided to all staff involved directly or indirectly in the provision of Products or Services to Cochlear. The Supplier shall implement controls to monitor on an ongoing basis compliance with its information security policy.

8.2. Access Control in a Physical Sense

The Supplier shall take reasonable measures to prevent unauthorized persons from gaining access to data processing systems for processing and/or using Cochlear Data. by implementing physical controls which may include (as appropriate):

a) an access control system (ID reader, magnetic card, chip card);

b) keys;

c) door locking (electric door openers etc.);

d) security staff, janitors; and

e) surveillance facilities (alarm system, Closed Circuit Television (CCTV) monitor)

8.3. Access Control to the IT System

The Supplier shall ensure that persons authorized to use the data processing system have only access to the data, which they are authorized to access by implementing measures such as:

a) differentiated access rights (profiles, roles, transactions and objects);

b) reports on access used;

c) access levels and access controls;

d) change control procedures; and

e) audit trails.

8.4. Access control to Data Controller Data

The Supplier shall ensure that persons authorized to use the data processing system have only access to the data, which they are authorized to access by implementing measures such as:

a) differentiated access rights (profiles, roles, transactions and objects);

b) reports on access used;

c) access levels and access controls;

d) change control procedures; and

e) audit trails.

8.5. Security Incident Management

The Supplier shall implement an appropriate security incident management process aligned with industry best practices, requiring, at minimum:

a) prompt investigation of any Security Incidents;

b) notification of Cochlear within the timeframe specified in this Addendum; and

c) provision to Cochlear and/or its designation representative with all reasonable access to Service Provider's systems, data, and logs as necessary for the purpose of understanding the circumstances of the Security Incident.

Security Incident for the purpose of this clause 8.5 shall be taken to mean any actual or suspected unauthorised or unlawful access, use, modification, processing, loss, destruction or disclosure of data or information relating to Cochlear, Products or Services.

9. Governing Law

This Agreement will be construed in accordance with the laws of New South Wales, Australia, and the Parties submit to the non-exclusive jurisdiction of the courts of New South Wales, Australia.