ZIMMER BIOMET Your progress. Our promise.	**SUPPLIER QUALITY AGREEMENT** **SUPPLIER NAME / LOCATION (TOWN & COUNTRY)**	**ZBV-AQF-FOR-022-09 (CF06028 rev 3)** **Doc ID :**

Remove the word Template from this agreement before filling out, and be sure to remove and replace the green text with the necessary information and make the text black and delete the sections not being used in this agreement.

Supplier Name:	Doing Business As:	Date:
Supplier #(s):	Address:	City:
State / Postal Code:	Country:	Implantable (Y/N):
Zimmer Biomet Contact and Title:	Email Address:	Telephone Number:
Supplier Contact and Title:	Email Address:	Telephone Number:

NOTE: This agreement is applicable for all Zimmer Biomet sites doing business with the supplier.

1. Background

In order to maintain the quality and regulatory compliance of all of its products and/or services, **Zimmer Inc., Biomet, Inc.,** its affiliates and subsidiaries **("Purchaser")** has determined it necessary to require each of its Suppliers to maintain certain quality assurance standards as provided herein.

2. Quality Systems and other applicable regulations and standards

Supplier will comply with the regulation- as far as applicable for Supplier for the respective product - of the current version of the Council Directive 93/42/EEC of 14 June 1993 concerning medical devices (the "MDD") and of the current version of the Medical Device Regulation (EU) 2017/745 (the "MDR"), as applicable in each case. Supplier shall help Purchaser to comply with these laws in any way possible, in particular by providing information and by cooperating with Purchaser (e.g. regarding information and other requests by authorities). In addition, Supplier shall comply and has complied with all laws, regulations and orders of all manufacture, import, export and safe of the end products. Supplier will maintain a compliant Quality Management Systems based on the product or service provided (e.g. 21 CFR Part 820, 21 CFR 58, 21 CFR 1271, ISO 17025, ISO 13485, or ISO 9001). The Supplier quality system review is part of the initial and ongoing assessments performed by **Purchaser**. Changes from an existing quality system pertaining to registration/certification and the supplied product or service will require the Supplier to notify the relevant **Purchaser** Contact Person in writing prior to the implementation of the change**.** Exhibit A gives guidance on supplier changes and will not be considered all-inclusive. External manufacturers of finished goods and contract labs will be registered and listed its products with the FDA and/or hold certification from an internationally known organization.

Supplier will make available their ISO or relevant certifications with any updates or re-certifications.

All applicable elements of a quality system are considered when **Purchaser** is making its determination whether a quality system is acceptable, including, but not limited to the following:

- Properly implemented quality procedures for production processing, including validation.
- Appropriate statistical techniques to analyze quality data and production effectiveness.
- Corrective and preventive action system with evidence that actions are effective in preventing and eliminating defects. These actions will be part of a continuous improvement action.

3. Audits

The Supplier will permit **Purchaser,** or its designee, to audit the Supplier's quality system upon receipt of written, advance notification.

- Supplier will be available to participate in quality assurance meetings at the Supplier's facility or at **Purchaser** to review and update the status of issues pertaining to product or process quality and reliability for the processes, services and/or products purchased by Purchaser.
- Supplier will grant all relevant Regulatory Agencies i.e. FDA, and ISO Notified Bodies, to whom **Purchaser** is accountable, access to its works, to audit the Supplier's facility and/or records, with or without issuance of advanced notification by the aforementioned organizations.
    - Supplier will notify **Purchaser**, via written correspondence to their **Purchaser** Contact, of any regulatory body i.e. FDA (FDA, competent authority or other regulating bodies) of an inspection that is scheduled or initiated at their facility.
    - Supplier will provide required details of any actions (e.g. correction, removal, FDA 483 or other regulatory inspection findings, any warning letter issued by FDA, etc.) that impact the products and/or services the Supplier provides to **Purchaser**.
- Unannounced audit expectations: ***(Delete if not considered a Critical Subcontractor)***
    - Supplier will permit unannounced audits with the caveat that require visitor screening, escorts, and recognition that total access may not be granted per the company's Technology Transfer Control Plan (or other procedural) requirements due to International Traffic in Arms Regulations (USA - ITAR 22 CFR 120-130) regulations.
    - The Supplier agrees to include in their Quality Management System, a procedure explaining the expectations of unannounced audits to include, but not limited to the following:
        - Immediate notification to responsible Purchaser representative via phone.
        - Notification of notified body of production windows and changes.
        - Coordination with Purchaser before and after the audit when Purchaser product is in scope of the audit.
        - Training of staff regarding responsibilities and requirements during unannounced audits.

4. Acceptance Activities Quality Records/Retention

Acceptance activities required by **Purchaser** for any particular finished goods or service via requirements that are contained in purchase specifications from **Purchaser:** included in or applicable to a purchase order, Statement of Work (SOW or contract) and Product Specifications, the Supplier will:

- Include in their Device History Record (DHR) documented inspected, tested, or otherwise product verification as conforming to **Purchaser** specified requirements.
- Include acceptance activity records of appropriate test/inspection criteria, validation records, revision level of documents/equipment/software used, operating procedures (planning, routing or traveler sheets), dates of test/inspection, and the results.
- Ensure records are stored in a manner to prevent mix-ups, along with stored in a manner to minimize deterioration and to prevent loss. Also, this would include electronic records.
- Retain records either onsite or through other means (including electronic or off-site storage) for a period of time equivalent to the expected life of the device, but in no case less than 15 years from the release date for commercial distribution of the product, but in no case less than 15 years from delivery of the product to Purchaser. Any electronic or off-site storage will be easily retrieved within at least 1 day from **Purchaser's** request.
- Notify immediately via written correspondence to the **Purchaser** Contact Person prior to disposing of any

records whether this is due to:
  - fulfillment of holding period
  - Cessation of business with **Purchaser** and provide notification of closing its facility, and supply (at the **Purchaser's request)** all requested manufacturing and quality related documents.
- Grant access to all manufacturing and quality records by **Purchaser** employees, agents, contractors and assigned either directly or by a third party within 2 working days of notice from **Purchaser**.
  - In certain instances (i.e. FDA investigations/inspections), these records may be required to be made available on the same day or within 24 hours of notice from **Purchaser**.
- Support Zimmer Biomet regarding technical documentation as defined in the MDD or MDR (as applicable), including but not limited to the results and critical analyses of all verifications and validation tests undertaken by the supplier on the Purchaser's product that demonstrates conformity of the product and services provided.

5. Compliance

Supplier will comply with all **Purchaser** specifications, including any industry standards such as ASTM, product listings or applicable print specifications, and any **Purchaser** quality program for supplier's (e.g. Supplier Certification, Skip Lot, or DTS) or requirements applicable to Supplier as **Purchaser** may develop. **Purchaser** reserves the right to amend and modify its supplier quality programs at any time without prior notice.

The Supplier will furnish a Certificate of Conformance (C of C) and/or a Certificate of Analysis (COA) with each product lot/shipment attesting to the conformance of the product to **Purchaser** Purchase Order (P.O.)/contract specifications, drawings and acceptance requirements and/or other **Purchaser** product requirements, as applicable to **Purchaser**.

Supplier will conform to the latest RoHS , REACH, and conflict materials restrictive substances as defined by United States Dodd-Frank Consumer Protection Act compliance standards and certify that the products provided to **Purchaser**, whether component, raw material, or finish good.

Per Medical Device Regulation (Regulation (EU) 2017/746 comply with Restricted Materials/Substances that are part of the Candidate list of Substance of Very High Concern (SVHC, REACH, Article 59 (10)) will be declared. This restriction also applies to all carcinogenic, mutagenic and/or reprotoxic substances (CMR) of category 1.A and 1.B, and, endocrine disruptors (ED) substances with serious effects to human health

Supplier will comply with the new Medical Devices Regulation (Regulation (EU) 2017/745) and certify that the products provided to Zimmer Biomet whether component, raw material, or finished goods, will integrate the requirements described in the Article 10.4 of the MDR (Annex I, General Safety and Performance Requirements).

The Supplier agrees to manufacture the Products in compliance with the EU Directive 722-2012 Animal Tissue used in the manufacture of medical devices or use of material of animal origin.

The Supplier agrees to comply with FDA regulation 21 CFR 801.437; Subpart H--Special Requirements for Specific Devices, Section 801.437 User labeling for devices that contain natural rubber. This section applies to all devices composed of or containing, or having packaging or components that are composed of, or contain, natural rubber that contacts humans. The term "natural rubber" includes natural rubber latex, dry natural rubber, and synthetic latex or synthetic rubber that contains natural rubber in its formulation.

6. Adverse Non-Conformance Product Event

Supplier will implement and maintain a documented system to quarantine, and report to **Purchaser** any product issue that may compromise the safety of the product user or diminish the quality of the product thereby warranting, ceasing continued shipment of the product or requiring a product recall.

- If Supplier becomes aware of any product complaints or adverse reactions that impact the products and/or services which are sourced by the **Purchaser**, the Supplier will immediately notify their **Purchaser** Customer Service team at 1-800-348-2759 or submit the complaint electronically to the **Purchaser** via **Purchaser** Product Experience Reporting (PER) process at zimmer.per@zimmerbiomet.com.
- The Supplier, if requested by **Purchaser**, will conduct internal investigations, record reviews, and sample evaluations as required to determine the validity of the complaint. The findings from the investigation will be reported to the **Purchaser** Contact Person within 5 working days of notice from **Purchaser** or within the

designated timeframe given by **Purchaser**.

- In the event **Purchaser** is required or voluntarily decides to recall or withdraw Product implicating a Supplier's processes as potential root cause, the Supplier will fully cooperate with **Purchaser** in connection with such a recall or withdrawal.
- Zimmer Biomet will be solely responsible for the reporting of adverse experiences with respect to the Product to the FDA and other global Regulating Bodies. Zimmer Biomet will be responsible for disposing of any recalled or withdrawn Product.

7. Supplier Corrective Action

Upon notice from **Purchaser** of any deficiency in supplier's quality system, product or service, the Supplier will provide documented corrective action(s) to prevent future deviations from the specification or quality system requirement.

- Upon **Purchaser** request, the Supplier will provide to the **Purchaser's** Supplier Quality team the established SCAR document and all supporting documents pertaining to the specific problem/defect description (including similar product), containment actions performed, and initial investigation performed. All documentation and actions performed will be provided within the required time necessary by the Purchaser's compliance system, which is ten (10) calendar days, or less if there is an impact to the Purchaser's supplied material or service.
- The Supplier will provide **Purchaser;** within the Supplier Quality established SCAR documented timeframe, the root cause analysis, and corrective/preventive action(s) taken to minimize any risk to the **Purchaser** and **Purchaser's** customers or end users of the product/service furnished by the Supplier.

8. Change Notification

The Supplier will provide written notification to the **Purchaser** of any changes referenced in Exhibit A and/or in the Supplier's quality system immediately using CP06013 Supplier Change Notification Template. This notification will be submitted in order for the **Purchaser** to evaluate the impact of the change to the quality of the finished product/service. See Exhibit A for a list of requirements on changes, which may require advance notification to **Purchaser.** This list may not be considered all-inclusive

- **Purchaser** respectfully requests a minimum of 120-day notice to ensure appropriate reviews can be completed, including any Regulatory evaluations.
- Supplier changes will be approved by **Purchaser** before the Supplier implements the change.
- Any impact to open Purchase Orders which are due to the change will be communicated to the **Purchaser's** Sourcing team in order to assess the impact on deliveries to the **Purchaser**.
- Any changes requested by the Supplier or by the **Purchaser** that may affect the supplier risk classification for the product/service they provide, will require an evaluation of the Supplier Quality Agreement to determine if the change impacts an existing Agreement. If changes are necessary a new Agreement will be initiated by the Purchaser to the Supplier
- The Supplier will notify the **Purchaser** of changes in the Supplier's Management structure via written correspondence, which may be in the form of a letter or electronic means.
    - Such changes includes, but are not limited to, changes in management with executive responsibility or changes in management responsible for regulatory, quality or quality systems.

9. Production/Process Controls

Supplier will ensure that all processes that directly affecting the quality of products and/or rendered services, are clearly defined and conforming to **Purchaser** purchasing specification requirements applicable to **Purchaser**. Supplier's process controls will include, but not limited to:

- Documented procedures defining the manner in which processes are to be performed and measured.
- Use of suitable equipment and environment to produce products or services.
- Monitoring and controlling of critical process parameters and product characteristics using in-process inspection and where appropriate, supporting with statistical methods. The evaluation of the produced products/rendered services will be performed per **Purchaser** established critical to quality (CTQ) dimensional requirements as signified through patient risk criticality.
- Supplier will be required to demonstrate risk mitigation of process risk per ISO 14971 (i.e., pFMEA (Process

Failure Mode Effect Analysis), or relevant risk management tools).

- Documented changes to production and process controls.
- Trained qualified personnel to perform operations on **Purchaser** products and/or executed services. For example, where certifications are required (i.e., Fluorescent Penetrant Inspection (FPI), X-Ray, welding, etc.) only certified operators are to perform these operations.
- Defined and controlled criteria for workmanship standards.
- System(s) to protect **Purchaser's** products from contamination by unapproved foreign materials.

10. Identification & Traceability

Supplier shall identify the product by suitable means throughout product realization and shall establish documented procedures for such product identification

Supplier shall ensure the traceability of the batches manufacture and establish documented procedures for traceability. Such procedure shall define the extent of product traceability and the records required.

A batch is defined as having resulted from the same process and undergone the same processes and treatments in the same period, for the same product reference and for a two raw materials batches.

11. Process Validation

For Supplier's processes or outsourced sub-processes that cannot be fully verified by subsequent inspection or test methods (e.g. Welding, brazing, heat treating, passivation, or anodizing), the Supplier, and their sub-tier supplier(s), will have an established validation process that meets the needs of the specified quality system, and will minimally consist of Installation Qualification (IQ), Operational Qualification (OQ), and Performance Qualification (PQ), and 21 CFR Part 11 compliance when applicable. Supplier's validation process will include:

- Appropriate statistical rationale for sampling strategy.
- Definition of equipment and process parameter requirements of validation IQ/OQ/PQ.
- A post-validation monitoring and control process defined by the Supplier and agreed upon by Purchaser.
- A process for evaluating changes against the current validated state of the process and a method detailing revalidation activities when required.
- The Supplier agreeing to notify **Purchaser** immediately if any validation process deviations occur. The Supplier will evaluate and analyze the deviation where appropriate, and provide the results to **Purchaser** for consideration for acceptance.
- A method, if requested, to provide validation protocols and results of pre-validation process development activities including any changes to processes or equipment for which the validation requirements have been established and mutually agreed upon.

12. Implantable Titanium Raw Material (Delete if site is not governed under current procedure for process)

The Supplier will only source titanium used in the Purchaser's implantable devices, from the Purchaser's defined Implantable Raw Material Approved Supplier List (ASL) or implantable materials referenced to that site as specified. This requirement will be forwarded to any of the Purchaser's Supplier's.

13. Supplier Sub-tier Contractors

Purchaser may require documented proof that the Supplier has ensured the effectiveness and adequacy of its sub-tier contractor controls. Upon such requirement, the Supplier will promptly furnish such documentation requested by **Purchaser** of its subcontractor's controls. The Supplier will ensure that subcontractors comply with all documented agreements including as a minimum:

- Methods for monitoring the subcontractor.
- Stipulations for obtaining from each subcontractor a duly signed and authorized written agreement, in which the subcontractor explicitly confirms its compliance with **Purchaser** purchasing specifications, including supplier change notification.
- Provisions of such agreement to **Purchaser.**
- Provisions for submission of any and all additional documentation to **Purchaser,** including but not limited to

process validation documentation.

- Suppliers and sub-contractors are not to knowingly work with distressed nations or nations that promote child labor.

14. Packaging and Shipping Methods

Supplier will, as deemed appropriate by **Purchaser**, implement and follow packaging, shipping methods necessary to prevent cosmetic, mechanical and electrical damage to the products shipped, as applicable. The Supplier will package the product as specified on the part drawing. If no packaging is specified on the part drawing, the Supplier will package the product so as to prevent damage or deterioration of the product and labels during shipment per **Purchaser** specified requirements.

15. Product Registration

Upon a Purchaser representative request, the Supplier will submit all non-proprietary information needed for registration of the product. The Supplier will ensure that Purchaser is involved in any changes, which may affect the Product's regulatory status. The Supplier will make available proprietary information to regulatory agencies through a master file or equivalent document in the English language.

16. Term

This Agreement will remain in effect from the date of the last signature affixed below and will continue until Purchaser determines a new agreement is necessary.

17. Miscellaneous

This Agreement is the complete, final and exclusive understanding of the parties as to the matters covered herein and supersedes any and all prior Supplier Quality Agreements. Notwithstanding the foregoing, this Agreement does not supersede or replace any separately negotiated quality agreement. To the extent that a conflict arises between this Agreement and a 3rd Party Agreement with more specific Quality and Regulatory terms, the 3rd Party Agreement supersedes all.

No amendment, modification or supplement of any provision of this Agreement will be valid or effective unless made in writing and signed by a duly authorized management representatives of each party. Neither party will have the right to assign any of its rights or obligations under this Agreement without the prior written consent of the other party.

No provision of this Agreement will be waived by any act, omission or knowledge of a party, its agents or employees.

This Agreement will be governed by and *interpreted in accordance with the laws of the (**State of XXX**), United States of America or (**Country of XXX**)*, without regard to its choice of law rules.

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By signing below, the Supplier and **Purchaser** agree to the terms hereof and the Supplier agrees to meet all requirements that apply for any and all products and services provided by the Supplier to **Purchaser.**

Supplier's Quality Management	**Supplier's Operations Management**
Printed Name	**Printed Name**
Title	**Title**
Date	**Date**
Signature	**Signature**

Zimmer Biomet Supplier Quality Management	**Zimmer Biomet Sourcing Management**
Printed Name	**Printed Name**
Title	**Title**
Date	**Date**
Signature	**Signature**

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Exhibit A

Type of Change or Activity*	Special and/or Validated Processes**	Implants and Implant Components	Non-Implants, Instruments	Raw Material, Mfg. Material	Packaging Manufacturer or Packaging Service	Engineering Services, Contractors Consultants, Distributors	Fixture-Gage, Test-Calibration, NDT	Sterilization, Microbiology
I) Production Facility Create new building, change buildings or move product to another location.	X	X	X	X	X	X	X	X
II) Equipment **Change type of equipment** Move to different equipment same technology, i.e. brand of equipment, Lathe to screw machine, manual to CNC, Change fume hood, etc.	X	X	X	X	X		X	X
Change to specific equipment with similar capabilities Move from Sealing machine serial number 123 to sealing machine serial number 456; change in NDT equipment.	X	X	X	X	X			X
Movement of equipment within a facility – that affects a validation.	X	X	X	X	X			X
Change/reduced frequency or method of Preventative Maintenance.	X							X
Change to Non-routine maintenance.	X							X
Change machine or tooling design.	X	X	X		X			X
Change machine program.	X	X			X			X
Change process parameters.	X	X	X	X	X			X
Packaging Materials or Packaging processing	X	X	X	X	X			X
Change featuring materials that come into contact with the product.	X	X	X	X				X
III) Subcontractor Change Move product, process, or service from in-house to subcontractor, Subcontractor to in-house, or from subcontractor A to subcontractor B.	X	X	X	X	X	X	X	X
IV) Change Inspection Requirements All changes in inspection method, frequency, sampling methods, etc. Note: changes that increase frequency or increase detect-ability, i.e. the use of equipment with higher accuracy and precision may be implemented with notification to Purchaser to follow.	X	X	X	X	X		X	X
V) Manufacturing Materials Change Manufacturing Materials that come in contact with the Product coolant, machine lubricants, polishing compound, cleaning solutions, etc.	X	X	X	X	X		X	X
VI) Manufacturing process flow re-sequencing, changes to established router, additions/deletions, etc.	X	X	X	X	X			X
VII) Rework and/or Reprocessing not outlined on the original approved Control Plan or Specification A loop added to route product back to a previous step for the purpose of repeating work done to bring product into specification.	X	X	X	X	X	X	X	X
VIII) Forming Operations Casting, forging, wrought operations as related to metals (e.g., changing configurations, release agents, mold, or die materials are reportable changes) and compression molding, ram extrusion, or injection molding as related to polymers.	X	X	X	X	X			
IX) Raw Material Change in formulation, purity, or strength (Including additives and percentages).	X	X	X	X	X			
X) Management Change Change in the Organizational Management structure. These changes include, but are not limited to, changes in management with executive responsibility, or changes in management responsible for the regulatory, quality or quality systems.	X	X	X	X	X	X	X	X
XI) Design Changes Design or design drawing changes that affect Zimmer Biomet product	X	X	X	X	X	X	X	X
XII) Software Change Changes in a software application that would affect a Zimmer Biomet product, product drawing or service. This would include software as an application for a medical device.	X	X	X	X	X	X	X	X
XIII) QMS Change All changes on the ISO certificate. These could include a change on the scope or the loss of the certificate.	X	X	X	X	X	X	X	X

* Exhibit A is a guide for reporting requirements for process and material changes and is not intended to be all inclusive.**Applies to processes where the results of the process cannot be fully verified by subsequent inspection and test. The process is to be validated with a high degree of assurance and approved according to established procedures.

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Ancienne codification *Old codification*	ZBV-AQF-FOR-022-08
Procédure Corporate de référence *Corporate reference*	CP06017

DM : X	**Pharma : X**

	Rédaction / *Redaction*	**Vérification / *Verification***	**Approbation / *Approval***
Date ***Date***	18 Nov 2019	Nov 19th, 2019	Nov 19th 2019
Nom / Fonction / Signature ***Name / Position / Signature***	***CORROY Antoine*** *Supplier Quality Manager*	***BOSSERT Yannick*** *Director QA/RC EMEA West Region*	***SARH Majdeline*** *QMS Manager* ***Meis-er-rym KESSAISSIA*** *Chief Pharmaceutical officer* Nov, 20th 2019

Services *(cochez la case si le service est destinataire)*			**Services** *(cochez la case si le service est destinataire)*		
Achats	ACH	☐	**Microbiologie**	MIC	☐
Affaires Réglementaires	AFR	☐	**Pharmaceutique**	PHA	☐
Bureau d'Etude	BDE	☐	**Planification / Approvisionnement**	LOG	☐
Cellule Evaluation Clinique	CEC	☐	**Production**	PRO	☐
Direction Générale	DGE	☐	**Qualification et Validation**	QVA	☐
Hygiène Sécurité Environnement	HSE	☐	**Qualité Fournisseurs**	AQF	X
Informatique	INF	☐	**Qualité Opérationnelle**	QOP	☐
Laboratoire	LAB	☐	**Qualité PMS / Réclamation Client**	PMS	☐
Magasin	MAG	☐	**Recherche & Développement**	RAD	☐
Maintenance	MAI	☐	**Ressources Humaines**	REH	☐
Méthodes	MET	☐	**Système Management Qualité**	SMQ	☐
Métrologie	MTR	☐			
Groupe Manager Valence		☐	**CODIR**		☐

Système Management Qualité ***Quality Management System***		
Date de mise en application ***Application date***	20 novembre 2019	**Signature + Nom /** ***Signature + Name :*** CAMATY Alyssa
Date limite de révision *Date de mise en application + 36 mois* ***Deadline review*** *Application date + 36 months*	Novembre 2022	

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ZimmerBiomet France revision history

Indice /Index	**Date /Date**	**Nature de la modification /Nature of the modification**	**N° de CAPA, NC, ou Change Control associé. / N° of CAPA, NC, or Change Control associated.**
07	21 Mars 20178	*En accord avec la procédure Maitrise de la documentation 05-001/ZBV-SMQ-PGE-009 il a été réalisé les modifications suivantes :* ▪ *Modification de la codification du document ainsi que de l'ensemble des références documentaires dans le corps du texte,* ▪ *Changement de la page de garde,* ▪ *Aucune modification du fond,* ▪ *Le changement de codification n'entraine pas de révision de l'indice qui est conservé.* *According to the Documentation Mastering procedure 05-001/ZBV-SMQ-PGE-009, the following modifications have been made :* - *Modification of the codification of the document as well as all the documentary references in the body of the text,* - *Changing the cover page,* - *No substantial change,* - *The codification change does not affect the index which is maintained.*	CAPA : CA-003324 Change Control : 2017-0204
08	30 July 2019	Integration of CF 06028 rev 3: On chapter 2- Quality systems: Add regulation MDD & MDR On Chapter 4 – Acceptance Activities : Add technical support regarding MDR & MDD	CC2019 -0236
09	14 Nov 2019	Add in the Exhibit A : part XIII) QMS Change.	CC2019 -0236

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Corporate REVISION HISTORY CF06028:

Rev	Revised by	Date Released	Description of Change
1	Doug Calvelage	See DC System	New release into Zimmer Biomet Corporate document template. Template is a combined document with legacy Zimmer global procedure ZMH-QMS-4-014 and Biomet template **CF0604** for best practice.
2	Doug Calvelage	See DC System	• Added instructions at top of page in green, to note as "Remove the word Template from this agreement before filling out, and be sure to replace the green text with the necessary information and make the text black and delete the sections not being used in this agreement". • Updated the information section requirements on the beginning of page one. • Added "**NOTE: This agreement is applicable for all Zimmer Biomet sites doing business with the supplier.** • Added "Make Available Their" and removed "Submit Updated" verbiage in the ISO line of Quality Systems section • Added the verbiage "Remove the word Template from this agreement before filling out, and be sure to remove ALL green text and any sections not being used in this agreement" in the unannounced audit information. • Added the word "knowingly" in the last bullet of the Supplier Sub-Tier Contractor Section • Added 2 new line items in Appendix A XI) Design Changes Design or design drawing change to product supplied to Zimmer Biomet XII) Software Change Changes in a software application that would affect a Zimmer Biomet product, product drawing or service. This would include software as an application for a medical device. • Changes requested from Sourcing peer review 9/12/17 Added table for agreement information at beginning of document to include the applicable information Added information to reference CP06018 Corporate Supplier Quality Guidebook on page one Capitalized Supplier throughout where the verbiage is possessive Updated verbiage in bullet points of Acceptance Activities Quality Records/Retention section Updated verbiage in first paragraph of Compliance section Updated verbiage in first and section bullets of Supplier Corrective Action section Updated verbiage in first paragraph of Change Notification section Updated verbiage in bullet points of Change Notification section, along with removing redundant bullets Updated verbiage in Implantable Titanium Raw Material and Supplier Sub-Tier Contractors section
3			•