

**Material Compliance Records Form**

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***Supplier Information***

Supplier Name
Address

***Compliance Contact***

Name
Title
Email Address
Phone Number

***Scope***

The responses provided on this form are to cover all products supplied by you (Supplier) to the Buffalo branch of any Nissha Medical Technologies business unit (collectively referred to as NMT). These business units include:

- Nissha Medical Technologies
- Graphic Controls Data Recording
- Graphic Controls Transactional Media

NMT acknowledges that Supplier may not be directly subject to some or all regulations identified below. NMT is therefore not seeking statements of compliance with regulations in their entirety and is instead seeking a statement on the presence of substances of concern. NMT expects that Supplier will act in good faith to address each declaration and question below to support the efforts of NMT and its customers in fulfilling their obligations under the applicable regulations.

NMT also acknowledges that Supplier will likely base its responses on the knowledge it has of its products and the information it receives from its suppliers. NMT does not require explicit verification of information provided by upstream suppliers but does ask that good-faith efforts are made by all parties involved.

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**Material Compliance Declarations**

Declaration #	Declaration	Yes	No	Explanation
1	<a href="#">Products comply with chemical content requirements of REACH. (Regulation (EC) No 1907/2006)</a>			
2	<a href="#">Products comply with chemical content requirements of RoHS 3. (2011/65/EU, amended by 2015/863)</a>			
3	<a href="#">Products comply with chemical content requirements of EU POP. (Regulation (EC) 850/2004)</a>			
4	<a href="#">Products DO NOT contain substances listed in section 10.4.1(a) or 10.4.1(b) of EU MDR. (Regulation (EU) 2017/745)</a>			
5	<a href="#">Products DO NOT contain substances above safe harbor levels as listed in California Proposition 65.</a>			
6	<a href="#">Products do not contain minerals from conflict regions (Section 1502 of Dodd Frank Act).</a>			
7	Sterile? If yes, provide sterilization method and the name and address of sterilizer.			
8	Biocompatibility Testing required? If yes, attached biocompatibility test results. If no, provide rationale.			
9	MRI Safe/Conditional? If yes, attached MRI Safe/Conditional Certificate. If no, provide rationale.			

**Material Compliance Questions**

Question #	Question	Yes	No	Explanation
1	Do any products contain bisphenol-S (BPS)?			
2	Do any products contain latex?			

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***Notification of Changes***

Declaration	Yes	No	Explanation
Supplier assumes the responsibility to proactively update NMT of any change(s) in status of any response(s) above.			

***Authorization***

Signature
Date

Please send this completed form and any accompanying documentation to [compliance@nisshamedical.com](mailto:compliance@nisshamedical.com).