

Document Inspiration Blenders EC Declaration of Conformance Revision ID8212

Suggested Upload Document Name: **Risk Assesment For Updating Document ID8212**

Completed by [Steve Hardaker](#) 14 Mar 2022

Reason for Risk Assesment

Uploaded latest version of the service manual for air-oxygen blenders to ISO Index and linked to technical files, received from Inspiration Healthcare 14/3/22.

Document Inspiration Blenders EC Declaration of Conformance Revision ID8212 is linked to the Following Standards and processes

Risk	Assesment Question	Does Update Risk Affect	Risk Frequency due to Update	Notes On Risk / Benefits statement if required	Further Action Required on Issue
8212Q0	Does this Update warrant updating Any External Parties due to any Terms and Conditional Agreements E.G. Notified Body or is the update a Significate change to any ISO Certifications	Does Update Risk Affect? No	Risk Frequency due to Update 1.Improbable Risk Likly Due to Update 1.Negligible Action Required: No Action Required	Notes On Risk / Benefits statement if required No requirement for Viamed to update any other parties. Manual is for internal use during servicing.	Further Action Required on Issue
8212Q1	Does Inspiration Blenders Technical file #57 Of type 3 require any Notificaions and/or Risk assesment updates due to this update	Does Update Risk Affect? No	Risk Frequency due to Update 1.Improbable Risk Likly Due to Update 1.Negligible Action Required: No Action Required	Notes On Risk / Benefits statement if required	Further Action Required on Issue
8212Q2	Final Notes	Official service manual created by the original equipment manufacturer (Bio-Med Devices) and provided by an authorised UK distributor (Inspiration Healthcare). Document superseded previous version. No appreciable risk.			

SAVE FORM

Only saves your progress in filling in above Questions - No feed back to pressing save form button

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