

Is my device a Reusable Surgical Instrument under the EU MDR(2017/745)?

Is my device a Reusable Surgical Instrument?

Reusable Surgical Instruments are defined as “instruments intended for surgical use in cutting, drilling, sawing, scratching, scraping, clamping, retracting, clipping or similar procedures, without a connection to an active device and which is intended by the manufacturer to be reused after appropriate procedures such as cleaning, disinfection and sterilization have been carried out.” (MDR Annex VIII, Chapter 1, 2.3).

Please use the table below to conclude if your define fits the definition.

Reusable Surgical Instruments				
		Device Name	Device Name	Device Name
From the intended use of the device (labeling (information supplied by the manufacturer) + clinical evaluation)		Yes/No, with justification	Yes/No, with justification	Yes/No, with justification
Is the device used for				
A	Cutting?			
B	Drilling?			
C	Sawing?			
D	Scratching?			
E	Scraping?			
G	Clamping?			
H	Retracting?			
I	Clipping?			
J	Procedure similar as the ones mentioned above?			



Reusable Surgical Instruments				
Is the device intended to be				
K	Connected to an active device?			
L	Reused after appropriate procedures such as cleaning, disinfection and sterilization have been carried out?			
Conclusion	(If the answer is yes for at least one of A-J, no for K and yes for L, then the device IS a Reusable Surgical Instrument)			