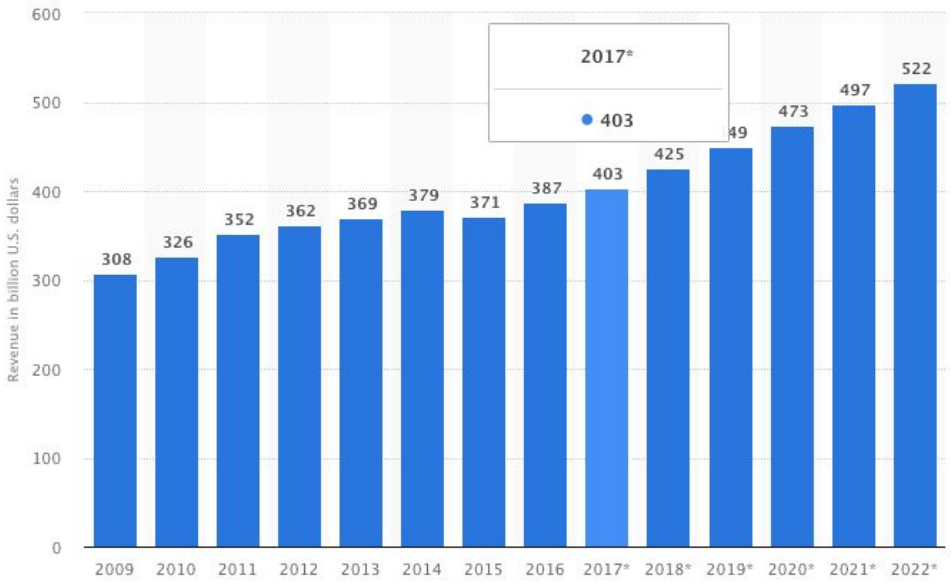
Med-Dev.io: An Introduction v1.3	
	By Stuart Corby
	December 2nd, 2017
The Global Medical Device Market	The global medical device industry is estimated to be worth approximately $403 billion dollars annually. Counterfeit, faulty or mislabelled Medical devices can seriously impact patient outcomes, including potential deaths so almost every country has applied some form of governmental controls over the sale and resale of devices within the industry. Global Medical Device Market - Source Statista 
Unique Labelling and Tracking	The latest iteration of these regulations is the requirement to uniquely label every medical device that is manufactured. This serialisation regulation was enacted in the US in September 2016 for all Type I and Type II devices, equating to 1,557,354 separate product lines as of the writing of this paper. Regulation is in force in some European countries and will be enforced EU wide by 2020. As the US market is approximately 40% of the global market (by value) and has already undergone the transition to unique identification, this introduction will use it as an example. Other implementations may vary by country but all carry similar constraints and requirements.
Med-Dev.io	The intention of Med-dev is to provide an open source blockchain service to allow all stakeholders in a medical device's lifecycle to make best use of these unique labels.
US FDA	In the United states the Federal Drug Administration now requires all medical devices to carry a unique device identifier (UDI) on their packaging. This identifier must be both machine and human readable. It must be issued by an accredited UDI

	issuing agency. There are currently three accredited agencies:
	  
Device Identifiers (DI's)	Once the manufacturer has registered with an agency they must request Device Identifier codes or DI's. These DI's represent a product line or SKU and each DI must be added to an FDA database called the GUDID along with some basic but vital information about what the product is and how to use it.
Unique Device Identifiers	As the manufacturer produces devices, it labels them with both the correct DI and an extra set of information that makes each label (and so each device) unique.
	While this process is laborious, most manufacturers have an expert within their team that understands both it and the requirements of other regulators for markets they sign into.
The FDA's Records	The FDA then, maintains records of the product line or DI and of the manufacturer. But the FDA does not record each unique device manufactured.
The Manufacturer's Obligations	Record keeping for each unique device falls to the the manufacturer, who must also know where that device is, if it is still in their inventory, or where they shipped it to, if they have sold it. So registering, updating the DI listing, keeping records of each UDI and where it is, or where it was shipped to, is the minimal regulatory requirement of any manufacturer that wants to sell type 1 or type 2 medical devices into the United States
Making good use of UDIs, now that they are on everything	Manufacturers however have other issues that unique identification can help them address. 1. Across the larger companies, inventory held averages 2.6 times annual turnover. 2. Inventory is most often held by distributors/agents or on consignment at hospitals and clinics, where it is held in reserve so that it is always on hand when needed. It is therefore hard to keep good track of the inventory. 3. Distributors and agents are good salespeople but not so great quartermasters - the best teams are frequently fined thousands of dollars (which come out of their bonus') by the manufacturers for failing to report their inventory accurately 4. Inventory often expires while in storage, when it could have been cycled into use prior to expiry if good records were kept. 5. In hospitals and clinics, it is left to administering staff to record which device is used on which patient. In some instances labels are removed packaging and attached to a nurse's scrubs during an operation, so they can later type the relevant codes into billing systems. 6. Maintenance is also improved with good tracking of UDI's. Simply knowing where a device was last scanned can help technicians find it in large hospitals when it is time for servicing. 7. Patients too can benefit from UDI. They can receive information direct from

	the regulator or the manufacturer when they receive a medical device and then again if there is a recall. They can also check a device is genuine (if full lifecycle tracking is in place)
Why use blockchain	Blockchain then offers all users of Medical Devices the ability to access information from regulatory authorities, check the providence of the devices they are taking possession of and to use the blockchain as a bridge that can keep all participants informed of the latest usage instructions, recall notices or advisories. It further allows both anonymous participation (for patients) and authorized usage to manage the sharing of data between teams.
	The blockchain will consist of a series of services that can be called upon by each other in order to provide and manage the data needed by participants. All interactions are then recorded and confirmed on the blockchain See Med-Dev Technical white paper for further details.
Conclusion	Keeping an absolute transaction log and record of each device as it takes its journey from manufacturer to patient through multiple disparate parties, with different needs, will save lives, reduce costs and allow participants to remain compliant to regulatory rulings. The medical devices industry is the ideal market for the application of low cost distributed electronic ledger. Unfortunately initial versions of blockchain, while promising in certain aspects, failed to provide transaction speeds, transaction volumes and transaction costs that were suitable to an industry which caters to extremely high value low turnover items as well as consumable devices that are manufactured in the millions. Blockchain 2.0 with the introduction of smart contracts has made the technology viable. Now, as speeds have increased and mining costs reduced (and/or removed by proof of stake), blockchain can now be effectively applied.